The Addition of Vitamins and Minerals to Foods

Proposed Policy Recommendations

Bureau of Nutritional Sciences
Food Directorate
Health Protection Branch

October 1999

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POLICY RECOMMENDATIONS FOR THE ADDITION OF VITAMINS AND MINERALS TO FOODS

1. It is recommended that:

   (a) the policy of addition of vitamins and minerals to foods to maintain and improve the nutritional quality of the food supply through (a) restoration and (b) nutritional equivalence of substitute foods be retained;

   (b) the use of mandatory food fortification programs continue to be employed as warranted to correct and/or prevent nutritional problems of public health significance which cannot be adequately addressed through voluntary means;

   (c) fortification programs be expanded to allow for a wider range of fortified products which would provide for more food sources of nutrients to help Canadians meet the Dietary Reference Intakes (i.e. where recommended intakes are not being met through current dietary practices); and

   (d) the category of special purpose foods be developed to allow for the addition of vitamins and minerals to foods to make a greater variety of products to fulfil a wide range of nutritional purposes.

2. It is recommended that addition of vitamins and minerals to foods not be permitted where no adequate nutritional rationale can be provided.

3. To avoid promoting consumption of foods that might increase risk factors for certain diseases or that have little nutritional value, it is recommended that criteria be applied to the selection of appropriate food vehicles for nutrient addition.

4. In the context of the recommendations stated above, the Codex General Principles should continue to be followed.

5. In implementing the above recommendations, it is proposed that increased flexibility be incorporated into the regulatory framework controlling the addition of vitamins and minerals to foods by including alternatives to the current "positive listing" approach. These might include general regulations and/or premarket notifications.

Table of Contents

1. **Introduction and Purpose of This Policy Review** 1

2. **Development of Policy on the Addition of Vitamins and Minerals to Foods – Consultation Process** 3

3. **Background** 5
   - What Roles Do Policies on the Addition of Vitamins and Minerals to Food Serve? 5
   - Federal Regulatory Policy 5
   - Current Context
     - (i) Canadian 5
     - (ii) Food and Drugs Act and Regulations 6
     - (iii) Practices in Other Countries 8
   - Other Considerations
     - (i) Labelling and Claims 8
     - (ii) Compliance Programs 8
     - (iii) Trade Considerations 9
   - Dietary Reference Intakes (DRIs) 9

4. **Issues Analysis** 10

5. **Guiding Principles and Criteria for Evaluation of Fortification Policy** 11

6. **Options Presented for Evaluation at the November 1998 Consultation Workshop** 13

7. **Summary of Policy Recommendations Concerning the Addition of Vitamins and Minerals to Foods** 14

8. **Analysis of Policy Recommendations Concerning the Addition of Vitamins and Minerals to Foods** 15
   - Recommendation 1(a) 15
   - Recommendation 1(b) 17
   - Recommendation 1(c) 19
   - Recommendation 1(d) 23

Recommendation 2 26
Recommendation 3 27
Recommendation 4 29
Recommendation 5 30

9. Implementation Plans 31

Appendices 32
Appendix A - Codex General Principles for the Addition of Essential Nutrients to Foods 32
Appendix B - Policy Review Time Lines 36
Appendix C - Interdepartmental Government Working Group 37
Appendix D - External Advisory Panel 39
Appendix E - Foods to Which Vitamins, Mineral Nutrients and Amino Acids May be Added (Sorted by Reason for Addition) 41
Appendix F - Trade Information Letter No. 351 45
Appendix G - Summary of Type of Regulatory or Legislative Controls on Addition of Vitamins and Minerals to Ordinary Foods in Various Countries 46
Appendix H - Canada's Obligations Under International Trade Agreements 48
Appendix I - Dietary Reference Intakes: Background Information 49
Appendix J - Clarification of Terms: Total Diet and Total Exposure 51
Appendix K - Risk Management 52
Appendix L - Disqualified Foods 53
Appendix M -Weighted Recommended Nutrient Intakes from Part D, Food and Drug Regulations, used as a basis for determining the significant nutrients in foods for purposes of restoration and substitute foods 54

1 Introduction and Purpose of This Policy Review

In January 1998, a comprehensive review of Health Canada's policies concerning the addition of vitamins and mineral nutrients to foods was announced. Addition of vitamins and mineral nutrients to foods is currently controlled by the Food and Drug Regulations[1] which specify the foods and the nutrients that may be added to them. A regulatory amendment is required each time either a new food or an additional nutrient is added to the list. The criteria for determining the acceptability of a nutrient addition to a food are based on the *General Principles for the Addition of Essential Nutrients to Foods* established by the Codex Alimentarius Commission (Codex)[2] (Appendix A, Section 3.1). The Codex General Principles are based on sound nutritional principles and provide standardized definitions of relevant terms.

The addition of vitamins and minerals to foods is an effective public health intervention which has been successfully used for many years to improve the nutritional quality of the Canadian food supply and to correct inadequate intakes of nutrients in both the general population and in selected groups. For example, the mandatory addition of vitamin D to milk and margarine has virtually eliminated rickets in children.

The science underpinning the policies for addition of vitamins and minerals to foods continues to evolve. This is reflected, for example, in the ongoing reassessment of nutrient requirements, involving most recently the collaborative efforts of Canadian and American scientists in the development of the Dietary Reference Intakes under the auspices of the U.S. National Academy of Sciences.

The current regulatory controls on the addition of vitamins and minerals to foods are viewed as overly restrictive by some sectors of the food industry and consumers. Many in these sectors would like to satisfy consumer demand for products available in the United States and other countries where there are fewer regulatory controls. They are seeking increased flexibility to increase Canadian business opportunities and to meet consumers' heightened interest in nutritious foods. As part of Regulatory Review, Health Canada agreed to conduct a review of these policies taking into account the public health role of nutrient addition to foods, consumer needs and industry concerns.

As a result of this policy review, the recommendations that are presented for comment in this paper incorporate a mechanism for recognizing recent and future scientific developments in the nutritional sciences. Furthermore, they provide a more flexible framework for realizing the potential benefits of addition of vitamins and minerals to foods, while maintaining the ability to address public health needs and protect the population from excessive or imbalanced intakes.

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[1] According to the Food and Drug Regulations: Part D, Division 1, vitamin means any of the following: vitamins A, D, E, K, C, thiamin (thiamine or vitamin B1), riboflavin (or vitamin B2), niacin, vitamin B6, folacin (folate), vitamin B12, pantothenic acid (or pantothenate) and biotin.

Part D, Division 2: In this Division, "mineral nutrient" means any of the following chemical elements, whether alone or in a compound with one or more other chemical elements: sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, iodide, chloride, copper, fluoride, manganese, chromium, selenium, cobalt, molybdenum, tin, vanadium, silicon and nickel.

[2] The Codex Alimentarius Commission was established to implement the FAO/WHO Joint Food Standards Programme. There are currently 165 member countries. The purpose of the Food Standards Programme is to protect the health of consumers and to ensure fair practices in the food trade. (See Appendix A.)

This document presents background information on the policy review and outlines the policy recommendations concerning the addition of vitamins and minerals to foods for stakeholder review and comment. Persons or organizations wishing to comment on these recommendations are asked to respond by December 31, 1999 to:

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Respondents are asked to provide a rationale for any changes to the recommendations that they wish to propose.

Please note that in keeping with our commitment to an open and transparent process, comments made to Health Canada as part of this consultation will not be considered confidential. However, the names of the individuals sending comments will be protected pursuant to the *Access to Information Act*. Public availability of comments will promote dialogue and understanding of the different points of view. The feedback we receive from this consultation will be considered in the development of the final policy recommendations concerning the addition of vitamins and minerals to foods.

2 Development of Policy on the Addition of Vitamins and Minerals to Foods – Consultation Process

ANNOUNCEMENT OF POLICY REVIEW

The length of the policy review was projected to be 18 months from its announcement in January 1998 (Appendix B). An Interdepartmental Government Working Group (WG) was formed, composed of representatives from various government groups whose work is impacted by this policy (e.g. Food and Therapeutic Products Programs in the Health Protection Branch of Health Canada, Health Promotion and Programs Branch of Health Canada, and the Canadian Food Inspection Agency) (Appendix C).

EXTERNAL ADVISORY PANEL FORMED

An External Advisory Panel (EAP) was established from nominations obtained from the food industry, consumers, disease-based and health associations, health professionals, academia and government. The 12 members were selected to represent a balanced mix of disciplines, skill sets, perspectives and geographical representation (Appendix D). The EAP has provided ongoing expertise and advice during all phases of this policy review.

ISSUES IDENTIFICATION

On March 27, 1998, a Consultation Workshop was held with a broad cross-section of stakeholders to help identify the issues of concern relating to this policy initiative. Approximately 85 participants attended, with a balanced representation from disease-based and health organizations, dietetic and other health professions, industry, consumers, academia and governments. The first steps taken at the meeting were to develop guiding principles for the review and to identify issues of concern. The issues identified fell within such diverse areas as public health, safety, consumer choice and availability, and trade and competitiveness. Not only were the objectives of the meeting met, but the consultation also succeeded in raising the awareness of all issues in these groups.

ANALYSIS OF ISSUES AND PREPARATION OF POLICY OPTIONS

The EAP and WG met for two days in June and again in September 1998 to continue work on the policy review. The objective of these meetings was to incorporate as many issues as possible that had been raised at the March Consultation Workshop into the development of potential policy option scenarios. The guiding principles were reviewed and collapsed into statements of objectives and outcomes for food fortification policies. The issues raised

TIMELINES

Policy Review Announced & Interdepartmental Government Working Group (WG) formed – *January 1998*

External Advisory Panel (EAP) formed – *February 1998*

Identify Issues of Concern to Stakeholders – Consultation, *March 27, 1998*

Analyse Issues & Prepare Options – EAP & WG, *Summer/Fall 1998*

Evaluate Food Fortification Options – Consultation, *November 23-25, 1998*

Prepare Policy Recommendations for Stakeholder Review & Comment – Release, *October 1999*

Close of Comment Period – *December 31,1999*

in March were reviewed and analysed and the key messages were used to develop criteria by which policy options (food fortification approaches) could be assessed.

A series of food fortification approaches was developed covering the full range of possibilities for adding vitamins and minerals to foods. The options ranged from the most restrictive to the free addition of vitamins and minerals to foods with varying amounts of government involvement. This series of food fortification approaches was considered and evaluated by the EAP and WG during their meetings.

EVALUATION OF FOOD FORTIFICATION OPTIONS

The potential approaches and their analysis were then presented in the background document, *Evaluation of Food Fortification Approaches*,[3] which formed the basis for discussions at a second Consultation Workshop held November 23 to 25, 1998. The objective of the November Consultation Workshop was to obtain input from a broad cross-section of stakeholders concerning the various food fortification approaches being considered. The background paper provided workshop participants with an overview of the development of criteria for assessing potential food fortification approaches and presented the approaches along with the analysis done by the EAP and WG at their two previous meetings.

PREPARATION OF POLICY RECOMMENDATIONS

The input and comments from the November Consultation Workshop and the analysis and advice of the EAP and WG have been used to help make the policy recommendations presented in this report. These policy recommendations were reviewed at a joint meeting of the EAP and WG on March 29 and 30, 1999. Implications for regulatory implementation of these recommendations were discussed by regulators from Health Canada and the Canadian Food Inspection Agency (CFIA) at a joint meeting on May 26, 1999.

[3] Health Canada, Health Protection Branch, Food Directorate. *Review of Health Canada's Policies Concerning the Addition of Vitamins and Minerals to Foods: Evaluation of Food Fortification Approaches – Background Paper*. This document can be viewed on Health Canada's Food Directorate website at:
<<www.hc-sc.gc.ca/food-aliment/english/subjects/dietary_reference_intakes/review_of_hc_policies/review_of_health_canada.html>>

3 Background

The following section provides a review of the background, history and context of food fortification policies.

WHAT ROLES DO POLICIES ON THE ADDITION OF VITAMINS AND MINERALS TO FOODS SERVE?

There are a number of reasons to set policies concerning the addition of nutrients to foods: they provide a uniform set of principles which, when applied, ensure a rational and consistent approach to the addition of nutrients to foods; they can be used to achieve the public health objectives of maintaining and improving the overall nutritional quality of the national food supply and addressing the nutritional needs of specific population sub-groups; and their application can avoid random nutrient addition which could lead to both excessive and inadequate intakes and create nutrient imbalances.

Codex[4] states that the General Principles for the Addition of Essential Nutrients to Foods are intended:

- To provide guidance to those responsible for developing guidelines and legal texts pertaining to the addition of essential nutrients to foods.
- To establish a uniform set of principles for the rational addition of essential nutrients to foods.
- To maintain or improve the overall nutritional quality of foods.
- To prevent the indiscriminate addition of essential nutrients to foods thereby decreasing the risk of health hazard due to essential nutrient excesses, deficits or imbalances. This will also help to prevent practices which may mislead or deceive the consumer.
- To facilitate acceptance in international trade of foods that contain added essential nutrients.

FEDERAL REGULATORY POLICY

The objective of Federal Regulatory Policy is "to ensure that government regulatory powers result in the greatest net benefit to Canadian society. Canadians view health, safety, the quality of the environment, and economic and social well-being as important concerns. The government's regulatory activity in these areas is part of its responsibility to serve the public interest."[5] Federal regulatory agencies must ensure that they can demonstrate that a problem or risk exists and that regulation is justified. They must provide timely and thorough consultation with interested parties and ensure that benefits outweigh the costs, adverse impacts on the economy and employment are minimized, and intergovernmental agreements are respected.

CURRENT CONTEXT

(i) Canadian

When synthetic vitamins and vitamin concentrates first became available in the 1930's and 40's, there were no restrictions on their addition to unstandardized foods in Canada. Regulations were introduced in 1941 to set minimum levels for some added vitamins in foods to prevent the consumer from being defrauded. In 1949, maximum levels were specified to prevent exposure to excessive amounts. Unstandardized foods could contain any added nutrients within the limits stated in the

[4] Food and Agriculture Organization of the United Nations. *Codex Alimentarius Volume 4 - Foods for special dietary uses (including foods for infants and children)*. 2nd edition. Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission. Rome, 1994. p. 9 (See Appendix A.)

[5] Treasury Board of Canada Secretariat. *Federal Regulatory Policy*, 1995.

Regulations. Standardized foods whose identity and composition are controlled by the Food and Drug Regulations (e.g. flour, bread, milk, salt) could not contain added vitamins and minerals unless they were specifically permitted in the standard. Iodization of salt was made mandatory in 1949 and vitamin D addition to evaporated and dried milks was permitted in 1950. Enrichment of flour was introduced in 1953 following the entry of Newfoundland into Confederation.

Experiences with vitamin D initiated further changes to the regulations on nutrient addition. During the 1940s and 1950s, any unstandardized food could be fortified with vitamin D at a minimum level of 400 IU and a maximum level of 800 IU per reasonable daily intake. A range of vitamin D–fortified products came onto the market, including fruit drinks, biscuits and cocoa mixes. A survey of children in Ontario in 1963 showed that many infants and young children were receiving over 2000 IU per day and that older children (8 years or over) could easily be exposed to 4000 IU, two-thirds of which came from supplements. At the same time that rickets continued to be a problem, there was concern that cases of infantile idiopathic hypercalcemia, thought to be related to high intakes of vitamin D, might increase. In 1964, action was taken to remove vitamin D from unstandardized foods in Canada. This was part of broader regulations that restricted the addition of vitamins, minerals and amino acids to only those foods identified in the Regulations (Part D). The restrictions on vitamin D addition resulted in an increase in rickets[6] because a fundamental principle of food fortification—the selection of an appropriate vehicle to reach the target population—had been overlooked. The addition of vitamin D to fluid milk in the late 1960s and early 1970s was successful in virtually eliminating rickets as a public health problem in Canada. In 1975, this fortification was made mandatory to ensure its universal application.

Vitamin D fortification represents an example of a successful fortification program that ensures a source of an essential nutrient in the Canadian diet and protects against excessive intakes. The addition of iodine to salt virtually eliminated endemic goitre associated with soils low in iodine in large areas of Canada. Vitamin C addition to evaporated milk has been responsible for the elimination of infantile scurvy in parts of Canada where evaporated milk continues to be used for infant feeding. Evaporated milk also comprises a significant dietary source of vitamins C and D in certain populations in the North and in Newfoundland.

The addition of vitamins and minerals to foods in Canada is permitted or required for other reasons besides fortification. The restoration of thiamine, riboflavin, niacin and iron to flour and other refined cereal products and vitamin A to fat-reduced milks contributes substantially to the intake of these nutrients. The principle of nutritional equivalence of substitute foods has been applied in setting requirements for products simulating meat, egg and poultry products, and most recently in determining levels of nutrient addition to plant-based beverages, such as soy beverages used in place of milk. Regulations controlling the amounts of vitamins and mineral nutrients in formulated foods used as sole sources of nutrition, such as infant formulas, meal replacements and formulated liquid diets, protect the users of those products from nutritional deficiencies or excesses.

(ii) Food and Drugs Act and Regulations

Addition of micronutrients to foods in Canada is strictly controlled as a result of the regulatory provisions promulgated in 1964 (Part D Division 3 of the Food and Drug Regulations). The authority for these regulations is the Food and Drugs Act, paragraph 4(a), subsection 5(1)

[6] Health Canada, Health Protection Branch. *Mandatory Addition of Vitamins A and D to Milk – Background Paper*, July 6, 1990. (Available from Nutrition Evaluation Division, Food Directorate, HPB)

and paragraph 30(1)(b).[7] The Regulations list the foods to which micronutrients may be added, the micronutrients and the levels to which they can be added to these foods (Appendix E). This is an example of a "positive listing" approach. The Regulations state the amount of nutrient that must be present in the food at the time of purchase. These Regulations apply to all foods sold in Canada, whether imported or domestically produced.

To add to the list of foods that may contain added micronutrients or to the list of nutrients, an amendment is required to the Food and Drug Regulations. To evaluate petitions for such amendments, the former Food and Drug Directorate of the Department of National Health and Welfare proposed guidelines which were published in 1971 in Trade Information Letter No. 351, *Proposed Guidelines for the Addition of Nutrients to Foods* (Appendix F).

These proposed guidelines were unchallenged and remained the basis for Canadian policy on the addition of nutrients to foods until June 1997 when new regulations providing for Interim Marketing Authorizations (IMA) (B.01.056) were promulgated. At that time, the Codex *General Principles for the Addition of Essential Nutrients to Foods* were incorporated by reference into the Regulations to establish the criteria that would be used for evaluating amendments proposed under the IMA provisions related to vitamin, mineral nutrient or amino acid addition to foods.

The IMA regulations provide a way "to allow a food not in compliance with [certain sections of] the Regulations to be marketed while an amendment to permit its on-going legal sale is being processed."[8] This means that foods containing added vitamins, minerals or amino acids for which no provision for such addition exists in the Regulations may be sold if an IMA has been issued. The issuance of an IMA, however, depends on the application satisfying the criteria that the addition is being done in accordance with the Codex *General Principles for the Addition of Essential Nutrients to Foods*. This review is essentially the same as the approach followed prior to the IMA regulations since the Codex Principles are very similar to the guidelines contained in the earlier Trade Information Letter No. 351. The IMA regulations only reduce the delay in getting products to market that meet proposed changes to the Regulations which have been accepted in principle, but for which formal publication in *Canada Gazette*, Part II may take several months longer.

When a proposed product is not in compliance with the Food and Drug Regulations and there is a need for data to be obtained through a controlled sale of the product to provide support for an amendment to the Regulations, a Temporary Marketing Authorization Letter (TMAL) may be issued in accordance with the Food and Drug Regulations (B.01.054). Such authorization is not intended to allow for a test market of a non-compliant product to determine if it is commercially successful. The type of data that might be needed in the case of a nutrient could include, for instance, information on

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[7] Paragraph 4(a) states:

No person shall sell an article of food that (a) has in or upon it any poisonous or harmful substance.

Subsection 5(1) states:

No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety

Paragraph 30(1)(b) states in part:

The Governor in Council may make regulations for carrying the purposes and provisions of this Act into effect, and, in particular, but without restricting the generality of the foregoing, may make regulations (b) …to prevent the purchaser or consumer thereof from being deceived or misled in respect of the design, construction, performance, intended use, quantity, character, value, composition, merit or safety thereof, or to prevent injury to the health of the purchaser or consumer.

[8] Health Canada. *Schedule No. 923 (Interim Marketing Authorization (IMA)), Regulatory Impact Analysis Statement*, Canada Gazette, Part II, July 3, 1997.

the users of the food, amounts consumed, and total amounts of the nutrient consumed. A product must be considered safe before being granted a TMAL. A TMAL is issued on a contractual basis and the area of distribution, the number of product cases, the commitment to do research and other details are part of the agreement.

(iii) Practices in Other Countries

The regulations governing addition of vitamins and mineral nutrients to foods vary widely from country to country. They range from free nutrient addition with only basic requirements for safety and labelling that do not mislead the consumer (e.g. Austria) to very limited addition controlled by the authorities (e.g. Italy). The regulatory possibilities include notification requirements and general permissions.[9] A table summarizing the regulations and practices in other countries is provided in Appendix G.

International food standards, guidelines and selected texts are elaborated by the Codex Alimentarius Commission whose membership currently consists of 165 countries, including Canada. These standards, guidelines and related texts are intended for voluntary adoption by member countries.

OTHER CONSIDERATIONS

(i) Labelling and Claims

Added micronutrients must be declared in the list of ingredients on food labels and the quantity of the added micronutrient present in the food must be disclosed. Exceptions are the vitamins and minerals added to certain foods (including margarine, flour and milk) when they are used as ingredients of other foods. The types of claims that are permitted respecting micronutrients on labels and in advertising of foods (and drugs) are strictly controlled under the Food and Drug Regulations. They are restricted to descriptive content claims (e.g. "good source", "excellent source") and to claims regarding generally accepted physiological functions (also known as biological role claims or structure/function claims). Health claims that relate micronutrients to the prevention or treatment of disease are prohibited on labels and in advertising of both drugs and foods. The issue of health claims for foods is currently being reviewed in a separate project.[10]

(ii) Compliance Programs

The CFIA carries out ongoing compliance and food inspection programs to verify that manufacturers and importers meet the Regulations for the addition of vitamins and minerals to foods and for associated labelling. Effective risk management is the collaborative responsibility of the CFIA and its industry and government partners.

In addition to using traditional inspection methodologies directed at finished food products, the CFIA is adopting a new inspection system based on the principles of Hazard Analysis Critical Control Points (HACCP). HACCP is a new approach to the management of chemical, physical and biological hazards that affect food safety. The key element of any HACCP-based system is the exercising of control throughout the manufacturing process at critical steps, called Critical Control Points (CCPs), before the food is packaged. This approach could be adopted for the inspection and

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[9] Nordic Council of Ministers, *Addition of Nutrients to Foods – Principles and Practices*, Copenhagen, TemaNord 1995:643.

[10] The final policy decision document of the Joint Food and Therapeutic Products Directorates Project on Functional Foods and Nutraceuticals may be found at: <<www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/ffn.html>>. To view the most recent developments in the implementation of the health claims policy, go to: <<www.hc-sc.gc.ca/food-aliment/english/index.html>>.

compliance programs regarding the addition of vitamins and minerals to foods.

(iii) Trade Considerations

Canada is a signatory to several bilateral and multilateral trade agreements, including the North American Free Trade Agreement and the Uruguay Round of Multilateral Trade Negotiations under the General Agreement on Tariffs and Trade 1994, leading to the WTO. These agreements recognize that protection of human health and safety are legitimate national objectives. A brief summary of Canada's obligations under international trade agreements can be found in Appendix H.

DIETARY REFERENCE INTAKES

The Food and Nutrition Board of the U.S. National Academy of Sciences is developing Dietary Reference Intakes (DRIs) for nutrients (see Appendix I). These are reference values that may be used for planning and assessing diets for healthy populations, and for many other purposes including judging the need for public health interventions such as food fortification and for formulating foods. Canadian scientists are participating in the review which is being supported in part by Health Canada. The reviews are being carried out sequentially for groups of related nutrients. The final report has been released for calcium and related nutrients (1999)[11] and a prepublication report has been released for the B vitamins and choline (1998).[12] As funding becomes available, additional reports will be released at various intervals over the next four years. The DRIs will ultimately replace the Recommended Nutrient Intakes in Canada and the Recommended Dietary Allowances in the U.S. The DRIs and the changes that can be expected over the next four years will clearly be relevant to the implementation of these policies on the addition of nutrients to foods.

The DRIs encompass the Estimated Average Requirement (EAR), the Recommended Dietary Allowance (RDA), the Adequate Intake (AI) and the Tolerable Upper Intake Level (UL). The first three values are defined by indicators of nutrient adequacy which may extend to reduction in risk of chronic disease or disorders where evidence is available; the fourth by indicators of excess where available. A report describing the risk assessment model used to establish the upper intake levels was published in 1998.[13] Further information and definition of these terms can be found in Appendix I.

[11] National Academy of Sciences, Institute of Medicine, Food and Nutrition Board, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*. Washington, D.C.: National Academy Press, 1999.

[12] National Academy of Sciences, Institute of Medicine, Food and Nutrition Board, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B_6, Folate, Vitamin B_{12}, Pantothenic Acid, Biotin, and Choline*. (Prepublication copy). Washington D.C.: National Academy Press, 1998.

[13] National Academy of Sciences, Institute of Medicine, Food and Nutrition Board, Subcommittee on Upper Reference Levels of Nutrients. *Dietary Reference Intakes. A Risk Assessment model for establishing Upper Intake Levels for Nutrients*. Washington D.C.: National Academy Press, 1998.

4 Issues Analysis

Several key issues of concern were identified during the stakeholder consultations. The issues fell into the areas of population health, safety, effectiveness, consumer choice and availability, and trade and competitiveness. They are summarized below.[14]

- **Population Health:** Vitamin and mineral addition to foods can be used to maintain and improve the nutritional quality of foods, and thereby protect and enhance the health of Canadians. Policies should be consistent with national nutrition standards and guidance, and public health initiatives. Policies on vitamin and mineral addition to foods should take into account population variability and changing demographics, and should be able to address simple nutrient deficiencies as well as the role of nutrients in reducing the risk of diet-related chronic diseases.
- **Safety:** The addition of vitamins and minerals to foods should not result in increased risk of health hazards due to nutrient excesses, deficits or imbalances. Various nutrients are associated with different adverse effects, both in the severity of the effect and in the margin of safety between requirement and the level at which adverse effects are observed. For some nutrients, little is known about this. Vitamins and minerals can also have an impact on the bioavailability and efficacy of other nutrients.
- **Effectiveness:** Effectiveness of vitamin and mineral addition to foods can include considerations of a technical nature, such as stability, bioavailability, colour, taste, etc., and a consideration of issues surrounding program effectiveness (i.e. the degree of success in reaching the population groups with identified needs while avoiding excessive intakes by other groups).
- **Availability and Choice:** Adequate choice in the food supply is needed to support healthy eating practices among a broad range of consumers, given the cultural, social, economic, demographic and health diversity of the Canadian population. Consumers are looking for more food choices, including fortified food products.
- **Trade and Competitiveness:** Canada is working toward improving international market access for Canadian food products. Some economists tell us that increased trade will benefit Canada's economy by increasing industrial growth, creating jobs and providing choices for consumers.

[14] Full details are available in the *Background Paper to Issues Identification* from the March 1998 stakeholder consultation workshop. This document can be accessed on the Health Canada website at: <<www.hc-sc.gc.ca/food-aliment/english/subjects/dietary_reference_intakes/review_of_hc_policies/review_of_health_canada.html>>

5 Guiding Principles and Criteria for Evaluation of Fortification Policy

With these issues in mind, the following guiding principles were developed during stakeholder consultations and with the assistance of the EAP.

Using these guiding principles, the EAP and WG reviewed the issues raised, considered the key elements and then developed criteria by which food fortification policy options could be assessed. The criteria developed were defined as either ***screen criteria*** (i.e. if the fortification approach did not pass all the screen criteria, it would not be assessed further), or ***managing/control criteria***. Screen criteria were intended to be mandatory, measurable and realistic. Managing/control criteria were more subjective and often less measurable. They represented desirable outcomes or characteristics that would help determine the appropriate level of control for a proposed fortification approach.

As a guide to understanding these criteria, a few of the statements were elaborated so that their meaning would be clearly understood.

Screen Criterion 1, helping "all Canadians achieve the recommended intakes," was clarified to indicate that this also includes vulnerable population sub-groups. This criterion links recommended intakes to the DRI process. In the derivation of the DRIs, the RDA, like the current

GUIDING PRINCIPLES FOR THE POLICY REVIEW CONCERNING THE ADDITION OF VITAMINS AND MINERALS TO FOODS

1. The policy must ensure that the addition of vitamins and minerals to foods maintains and improves the nutritional quality of the food supply in a manner that is consistent with public health priorities, goals and education programs. It must also aim to protect and enhance the health of the population, including sub-groups at identified risk.
2. The policy must ensure that the addition of vitamins and minerals to foods does not result in health hazards due to nutrient excess, deficits or imbalances. The policy should differentiate nutritional from pharmacological effects.
3. The policy must ensure that decisions are based on the best available evidence.
4. The policy must help to prevent practices that may mislead, deceive or confuse the consumer, and yet facilitate consumer choice.
5. The policy must be flexible enough to respond to the varied and changing demographics and food habits of the Canadian population, and reflect Canadian cultural and social values.
6. The policy must be practical, feasible, effective, enforceable and sensitive to trade and competitiveness issues.

Note: Principles are in order of priority although they are intertwined.

CRITERIA FOR EVALUATION OF POLICY OPTIONS CONCERNING THE ADDITION OF VITAMINS AND MINERALS TO FOODS

Screen Criteria

1. Must aim to help all Canadians achieve the recommended intakes (as developed in the DRI process) in line with the principles of a total diet.
2. Must be based on a risk management approach grounded in current science which takes into consideration:
   - recognized Upper Limits
   - nutrient interaction(s)
   - current consumption patterns in the context of total exposure.

Managing/Control Criteria

1. Permit a wider distribution of vitamins and minerals in the food supply to enhance consumer choice and availability.
2. Should encompass the principles of Codex and the DRIs.
3. Ensure that trade agreement obligations are met.
4. Allow the addition of a nutrient to a food, where the addition has no defined health benefit but poses little risk, so as not to impede trade and competitiveness.
5. Prevent practices that may mislead or deceive the consumer, and yet facilitate consumer choice.

Canadian RNIs, considers the role of nutrients in reducing risk of disease and developmental disorders and not just the evidence for the traditional role of nutrients related to deficiency diseases (Appendix I). The principles of total diet and total exposure, as they relate to this criterion, were also elaborated (Appendix J). This was done because it was felt that it would be inappropriate to encourage the consumer to consume 100% of the RDA through one food or to discourage choosing a variety of foods to meet total dietary needs.

During discussions surrounding Screen Criterion 2, "Must be based on a risk management approach...", several questions were raised about using this criterion. For example, what if there are insufficient data? (e.g. upper limits have not been established for some nutrients; data on nutrient interactions may not be complete; national food consumption data may not be complete). It was clarified that a risk management approach (Appendix K) would be used as it considers all these issues and uses the best available evidence.

Managing/Control Criterion 2 was included to help ensure that the benefits of adhering to the Codex General Principles are not lost while allowing the addition of vitamins and minerals to foods to be used both to prevent or correct deficiencies and to help Canadians meet the DRIs.

6 Options Presented for Evaluation at the November 1998 Consultation Workshop

A wide range of approaches to adding vitamins and minerals to foods was developed and evaluated by the EAP, WG and stakeholders during the November 1998 stakeholder consultation.[15] These covered the full range from a very restrictive approach to the free addition of vitamins and minerals to foods. They were arranged approximately in order of a progressive expansion of nutrient addition to foods with decreasing levels of government involvement. It was envisioned that the final Canadian policy for the addition of vitamins and minerals to foods would incorporate a number of these approaches.

FOOD FORTIFICATION APPROACHES EVALUATED AT THE NOVEMBER 1998 CONSULTATION

1. Maintain nutritional quality of foods through a) restoration, b) nutritional equivalence of substitute foods.
2. Retain mandatory food fortification programs to prevent deficiencies.
3. Expand fortification programs to improve the nutritional quality of the food supply: Public health approach to meet DRIs ➡ recognize optimal health approach (i.e. situations where new "nutritional recommendations" have increased and are not being met through current dietary practices).
4. Fortification of special purpose foods targeted to a specific population group or market.
5. Fortification programs to enable foods to be equivalent to moderate vitamin and mineral supplements; that is, allow fortification beyond demonstrated/ proven public health needs (e.g. fortification between ~60% and 100% of RDA per serving).
6. Addition of vitamins and minerals beyond clear health benefit but within safety range (e.g. > 100% of RDA per serving but < Upper Limits per day).
7. Free addition of vitamins and minerals as food ingredients as long as no health hazards exist and labelling does not mislead or deceive.
   With implementation options:
   A) positive list of low-risk nutrients,
   B) negative list of non-permitted nutrients, or
   C) no list – only control after problems arise.

A series of policy recommendations concerning the addition of vitamins and minerals to foods was then developed using the "pros and cons" associated with these various options. They are presented in the following section.

[15] *Synopsis of Plenary Sessions. November 24 and 25, 1998 Stakeholder Consultation - Evaluation of Food Fortification Approaches*. This document is available on the Health Canada website at: <<www.hc-sc.gc.ca/food-aliment/english/subjects/dietary_reference_intakes/review_of_hc_policies/review_of_health_canada.html>>

7 Summary of Policy Recommendations Concerning the Addition of Vitamins and Minerals to Foods

This section lists the policy recommendations concerning the addition of vitamins and minerals to foods. These recommendations reflect the evaluation and review provided to Health Canada at the November 1998 consultation as well as the analysis and advice of the EAP and government WG. The rationale supporting each of these recommendations is provided in Section 8 in addition to a description of the implications that these policy recommendations would have on the Canadian food supply and on regulations governing the addition of vitamins and minerals to foods.

1. It is recommended that:
   (a) the policy of addition of vitamins and minerals to foods to maintain and improve the nutritional quality of the food supply through (a) restoration and (b) nutritional equivalence of substitute foods be retained;
   (b) the use of mandatory food fortification programs continue to be employed as warranted to correct and/or prevent nutritional problems of public health significance which cannot be adequately addressed through voluntary means;
   (c) fortification programs be expanded to allow for a wider range of fortified products which would provide for more food sources of nutrients to help Canadians meet the Dietary Reference Intakes (i.e. where recommended intakes are not being met through current dietary practices); and
   (d) the category of special purpose foods be developed to allow for the addition of vitamins and minerals to foods to make a greater variety of products to fulfil a wide range of nutritional purposes.
2. It is recommended that addition of vitamins and minerals to foods not be permitted where no adequate nutritional rationale can be provided.
3. To avoid promoting consumption of foods that might increase risk factors for certain diseases or that have little nutritional value, it is recommended that criteria be applied to the selection of appropriate food vehicles for nutrient addition.
4. In the context of the recommendations stated above, the Codex General Principles should continue to be followed.
5. In implementing the above recommendations, it is proposed that increased flexibility be incorporated into the regulatory framework controlling the addition of vitamins and minerals to foods by including alternatives to the current "positive listing" approach. These might include general regulations and/or premarket notifications.

8 Analysis of Policy Recommendations Concerning the Addition of Vitamins and Minerals to Foods

RECOMMENDATION 1(a)

It is recommended that the policy of addition of vitamins and minerals to foods to maintain and improve the nutritional quality of the food supply through (a) restoration and (b) nutritional equivalence of substitute foods be retained.

EXPLANATION AND INTENT

Restoration and nutritional equivalence of substitute foods are currently considered valid reasons for the addition of vitamins and minerals to foods in Canada. There are many examples of their current application (for detailed listing, see Appendix E, Parts I and II). The Codex General Principles[16] state that restoration and providing for nutritional equivalence of substitute foods (for definitions see Appendix A, Sections 2.6, 2.3 and 2.4, respectively) are appropriate purposes for nutrient addition to foods. Canada also recognized these objectives as appropriate reasons for adding nutrients to foods in guidelines published in 1971 in Trade Information Letter No. 351 (Appendix F).

RATIONALE IN SUPPORT OF THIS RECOMMENDATION

The rationale for this recommendation is summarized in the following paragraphs:

Population Health (Screen Criterion #1)

This recommendation is aimed at maintaining the nutritional quality of the national food supply. During consultation with stakeholders, the consensus was that having the means to preserve the nutritional quality of the national food supply is essential and must be maintained. Ensuring that nutrients lost during manufacturing processes are restored (restoration) and that foods manufactured and represented as substitutes for existing key foods provide an equivalent amount of vitamins and minerals is consistent with this criterion. Public health considerations would continue to be used to decide whether the restoration of nutrients to a given food or the addition of nutrients to a substitute food should be mandatory or optional.

Safety and Effectiveness (Screen Criterion #2)

The levels of addition of vitamins and minerals to foods under this recommendation are tied to the "natural" or inherent levels of nutrients that are found in the food supply. This approach has a long history of safe and effective use in Canada.

Examples of restoration programs in Canada include:

- vitamin A added to all fat-reduced cow's milk (partially skimmed, skim)
- thiamine, riboflavin, niacin and iron added to white flour

Examples of nutrient addition for nutritional equivalence of substitute foods in Canada include:

- vitamins and minerals added to simulated meat products and products simulating whole egg
- vitamin A added to margarine and other similar substitutes for butter

[16] Food and Agriculture Organization of the United Nations. *Codex Alimentarius Volume 4 – Foods for special dietary uses (including foods for infants and children)*. 2nd edition. Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission. Rome, 1994. pp. 9-12. (See Appendix A.)

[17] "The *Tolerable Upper Intake Level* (UL) is the highest

Availability and Choice (Control Criterion #1)

This recommendation provides consumers with more food choices while maintaining nutritional adequacy. The restoration of vitamin A to fat-reduced cow's milk is an example of how an important nutrient is being restored to the milk so that the consumer is provided with a choice of milk products of varying fat content without having to sacrifice nutritional quality. Vitamin A is added to margarine, a substitute for butter, so that the consumer has a choice in fat spread products without losing the vitamin A value of the food being replaced.

This managing and control criterion indicates that the option should permit a wider distribution of vitamins and minerals in the food supply. Allowing the addition of nutrients to foods that are substitutes for nutritious foods to make them nutritionally equivalent does this by increasing the number of foods with the same nutritional profile available to the consumer. On the other hand, it does not increase the distribution of vitamins and minerals among foods within a diet since these foods just replace another food having the same nutritional profile.

Neither restoration nor making substitute foods nutritionally equivalent is mandatory in all applications; in several instances, the consumer can choose versions of a product with or without added vitamins and minerals. An example of this with respect to restoration is the availability of enriched and unenriched pasta. Also, plant-based beverages which may be used in place of milk may be fortified or not.

Codex General Principles (Control Criterion #2)

The principles surrounding nutrient addition for the purposes of restoration and for nutritional equivalence have been elaborated in the *General Principles for the Addition of Essential Nutrients to Foods* (see Appendix A, Sections 4 and 5). Canadian policies are consistent with these sections.

Trade and Competitiveness (Control Criteria #3 and #4)

This recommendation can have positive or negative impacts on trade depending on whether levels of vitamins and minerals set by the regulations are equivalent between trading partners.

Consumer Protection (Control Criterion #5)

Labels of products to which nutrients have been added must list the added nutrients and the amounts present in the food. If a product has vitamins or minerals added for restoration purposes, the amounts that must be added are currently controlled by the Food and Drug Regulations. Sometimes, several specific nutrients must be added if any one nutrient is added, while in other cases, one or more of the listed nutrients may be added at the stated levels. Definitions are also used to reduce the potential for misleading consumers regarding the nutritional value of a product with added nutrients. The terms "fortified" and "enriched" may be used only to refer to the addition of vitamins, minerals and other nutrients and not food ingredients or components. For some foods, to use the terms "fortified" or "enriched," a defined set of nutrients must have been added to the levels stated in the Regulations.

IMPLICATIONS FOR IMPLEMENTATION OF THIS RECOMMENDATION

Education

There may be a need for further consumer education to help them understand what substitute foods are and their role in the total diet, and how to choose between products with or without added nutrients.

Regulatory Implementation Issues

While recommendation 1(a) is for current policies to be retained, there is potential for alternative regulatory mechanisms that would make their application more flexible. This could be done by writing general regulations

that would permit manufacturers to add vitamins or mineral nutrients for restoration purposes or to make a substitute food nutritionally equivalent to the food it is intended to replace.

With respect to general provisions for restoration, there are already criteria that have been applied on a case-by-case basis that could be incorporated into the Regulations. These criteria follow the Codex General Principles. For example, the Principles advise that, for restoration, a food should be considered a significant source of an essential nutrient if the nutrient is present in a reasonable daily intake of the food prior to processing, storage or handling at 10% or more of the recommended nutrient intake (or in the case of an essential nutrient for which there is no recommended intake, at 10% of the average daily intake). The choice of which nutrients to restore may be modified by whether there is a demonstrated public health need. From a public health point of view, key foods identified as significant sources of energy and/or essential nutrients would likely be required to have nutrients restored on a mandatory basis, as is currently the case for thiamin, riboflavin, niacin and iron in white flour and vitamin A in skim milk. Other foods may be less important sources of nutrients on a population basis and restoration could be optional. It is for the latter group that a general regulation would be designed. Food standards may limit the application of such provisions, although a means for overcoming this problem was found in the case of standardized egg products (B.22.038). Introducing general regulations would involve establishing broadly applicable criteria for restoration (i.e. to determine which nutrients may be restored, cut-off points for restoration, etc.).

The applicability of similar general provisions will be examined for substitute foods. For substitute foods, the principles are similar except that, according to the Codex General Principles, the critical level at which a nutrient should be considered significant is 5% of the recommended nutrient intake in a serving or per 100 kcal of the food. The Regulations defining simulated and extended meat and poultry products and controlling their nutritional quality (Food and Drug Regulations: Divisions 1, 14 and 22) will be reviewed to determine if the definitions and the mandatory requirements for an extensive list of vitamins and minerals are still appropriate. Consideration could be given to a regulatory approach similar to that used for fortified plant-based beverages (i.e. having a required core list of nutrients and a set of optional nutrients). The Regulations for fruit juice substitutes in Division 11 will also be reviewed.

RECOMMENDATION 1(b)

It is recommended that the use of mandatory food fortification programs continue to be employed as warranted to correct and/or prevent nutritional problems of public health significance which cannot be adequately addressed through voluntary means.

EXPLANATION AND INTENT

Mandatory food fortification programs have a long and successful history as a public health intervention in Canada and many other countries. Application of this recommendation is intended to be used in situations to correct and/or prevent nutrition problems of public health significance which cannot be adequately addressed through voluntary means. During stakeholder consultation, there was unanimous agreement that this continues to be a valid reason for the addition of vitamins and minerals to foods.

The intent and principles surrounding this recommendation have been elaborated in the Codex General Principles, and relate to the following requirements: evidence of demonstrated need; selection of an appropriate vehicle to reach the population at risk; choosing a vehicle whose intake is known to be stable and uniform; and selecting an amount that is sufficient to prevent the nutritional

problem and at the same time, minimize the risk of excessive intakes.

RATIONALE IN SUPPORT OF THIS RECOMMENDATION

Population Health (Screen Criterion #1)

Mandatory food fortification programs are fundamental to Health Canada's public health role in correcting or preventing significant nutritional problems and hence contributing to the health of Canadians.

Several examples are provided to illustrate the types of nutritional problems that have been addressed through mandatory food fortification programs. Vitamin D is added to all except "industrial" cow's milk (i.e. fluid, powdered, concentrated or evaporated) as there are few sources of vitamin D in the Canadian diet and exposure to sunlight cannot be relied upon to supply sufficient vitamin D. Rickets due to vitamin D deficiency in children practically disappeared when vitamin D–fortified fluid milk became universally available. Similarly, large areas of Canada have soils low in iodine and mandatory addition of iodine to table salt has virtually eliminated endemic goitre. Further examples are listed in Appendix E, Part III, Fortification.

Safety and Effectiveness (Screen Criterion #2)

The decision to make vitamin or mineral addition mandatory in Canada is a scientifically based risk management decision based on several factors, some of which may be unique to the Canadian situation. The Codex General Principles provide guidance in making this risk management decision.

Availability and Choice (Control Criterion #1)

Mandatory addition in effect reduces consumer choice by denying the option of obtaining an unfortified version of the product. For this reason, such interventions are carefully assessed to ensure that the public health benefit outweighs the loss of consumer choice.

Codex General Principles (Control Criterion #2)

This recommendation is consistent with Sections 2, 3 and 6 of the Codex *General Principles for the Addition of Essential Nutrients to Foods* (Appendix A) and they will continue to be applied.

Trade and Competitiveness (Control Criteria #3 and #4)

Under existing trade agreements, it is recognized that countries have the right to take measures necessary for the protection of human life or health. Programs are developed with Canadian food consumption patterns in mind and an application of mandatory vitamin and mineral addition under this recommendation is therefore provided for under these agreements.

Consumer Protection (Control Criterion #5)

This recommendation is primarily a public health intervention tool and inherently provides for a high level of consumer protection in regulations governing the level of added vitamins and minerals.

IMPLICATIONS FOR IMPLEMENTATION OF THIS RECOMMENDATION

Need for Research and More Data

With changing demographics, eating patterns and food choices, there is a need for better and ongoing information on the nutrient intakes of Canadians. No data are available on the nutrient intakes and food consumption patterns of children or very elderly persons, nor are there national data on nutritional status of Canadians in general.

Regulatory Implementation

Recommendation 1(b), which is for the continued use of mandatory food fortification programs to correct and/or prevent nutritional problems of public health significance, will be applied as warranted on a case-by-case basis, as in the past. At the present time, no specific regulatory changes in this area are planned, although as final

DRI reports are released, they will be evaluated to determine if there is a need for further mandatory nutrient additions to foods, or if other nutritional interventions are necessary.

RECOMMENDATION 1(c)

It is recommended that fortification programs be expanded to allow for a wider range of fortified products which would provide for more food sources of nutrients to help Canadians meet the Dietary Reference Intakes (i.e. where recommended intakes are not being met through current dietary practices).

EXPLANATION AND INTENT

This recommendation recognizes the role that expanding the range of food choices with added vitamins and minerals can play in helping Canadians meet the DRIs. Products would be fortified such that the general population should be able to consume them safely without special labelling or directions for use. Products requiring special labelling to indicate the target user and purpose would have to meet the conditions outlined under Recommendation 1(d) for special purpose foods. As a result of this recommendation, both Health Canada and industry can be proactive. As further DRI reports are released, application of this approach to help Canadians meet their nutrition recommendations will continue to be refined. Regulations resulting from this recommendation would be voluntary in nature. When a nutritional problem is identified and considered to be of public health significance, Recommendation 1(b) will continue to be the preferred approach. The use of nutrients in the treatment, mitigation or cure of a disease or disability is not considered in setting the DRIs and is therefore not part of this recommendation or any others in this document.

This recommendation relates to the role of the RDAs and AIs (see Appendix I for definitions) as levels of intake recommended for individuals, as opposed to the use of the DRIs for assessing the nutritional status of populations. While it is not correct to assume that everyone who does not obtain the RDA or AI for a nutrient recommended for his or her age and sex group is deficient, it is not possible to determine the amount of a nutrient that any given individual needs. Therefore, all healthy individuals are advised to obtain the RDA or AI for their age and sex group.

Implementation of this recommendation will have to be nutrient-specific (i.e. dependent upon the risk profile of the nutrient). For example, for some nutrients a relatively high degree of control will continue to be needed to limit the risk of excessive intakes, while other nutrients could be subjected to less stringent regulatory controls.

RATIONALE IN SUPPORT OF THIS RECOMMENDATION

Population Health (Screen Criterion #1)

This recommendation would increase the likelihood that members of the general population or population sub-groups would meet the recommended intakes for their age and sex groups by allowing for a wider range of fortified food products. It should be noted that DRIs are intended for the healthy population and food products fortified with this objective in mind should be suitable for consumption by the general population.

Safety and Effectiveness (Screen Criterion #2)

The amounts of nutrients and the food fortification vehicles are expected to be determined based both on evidence of safety and on the objective of helping Canadians meet the DRIs. The addition of vitamins and minerals to foods should not result in increased risk of health hazards due to essential nutrient excesses, deficits or imbalances. It must be noted that nutrients may be associated with adverse effects that vary in their nature and severity and that nutrients vary in the margin of safety between the level of requirement and the level at which adverse

effects are observed. For some nutrients, little is known about the limits of safe intake. Vitamins and minerals can also affect the bioavailability and efficacy of other nutrients. Health Canada intends to recognize and use the Tolerable Upper Intake Levels (the ULs)[17] being established by the National Academy of Sciences, Food and Nutrition Board based on these considerations.

To ensure safety, implementation of this recommendation would require that levels be established as appropriate to the risk profile of each nutrient. With such a system, more latitude for addition of nutrients with a lower risk profile could be expected. Other nutrients for which there is a narrower margin of safety between the required level and the UL will likely have lower maximum levels and/or be restricted to certain food vehicles. In both cases, risk management will consider total oral intakes from all sources. (See also "Regulatory Implementation," for this section.)

Availability and Choice (Control Criterion #1)

An expanded fortification program would allow for a wider range of fortified products which would provide consumers with more food sources of specific nutrients. This recommendation would provide greater choice, as both fortified and non-fortified versions of the same foods would likely be available.

Codex General Principles (Control Criterion #2)

Section 3 of the Codex General Principles will be followed as a guide. Section 6 of the Codex General Principles, however, will be applied less rigorously than in Recommendation 1(b) with respect to need (6.2.4), but not with respect to safety (6.2.3 and 6.2.5). (See Appendix A for details.)

Trade and Competitiveness (Control Criteria #3 and #4)

This recommendation addresses some trade concerns by allowing more products with a variety of enhanced nutritional profiles. This will not necessarily, however, achieve complete harmonization with U.S. fortification levels. In the implementation of Recommendation 1(c), when establishing nutrient levels, it would seem most scientifically sound to base decisions on the latest authoritative statements such as the Dietary Reference Intakes (DRIs). U.S. manufacturers tend to use the Reference Daily Intakes contained in the Code of Federal Regulations when deciding upon fortification levels. Most of these are based on the 1968 Recommended Daily Allowances (RDAs) of the National Academy of Sciences. While manufacturers in the U.S. are not required to follow the Reference Daily Intakes when fortifying, the fact that these Reference Daily Intakes are also the standard for declaring the contents of vitamins

level of daily nutrient intake that is likely to pose no risks of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the risk of adverse effects increases. The term *tolerable intake* was chosen to avoid implying a possible beneficial effect. Instead the term is intended to connote a level of intake that can, with high probability, be tolerated biologically. The UL is not intended to be a recommended level of intake. There is no established benefit for healthy individuals if they consume nutrient intakes above the RDA or AI. ULs are useful because of the increased interest in and availability of fortified foods and the increased use of dietary supplements. ULs are based on total intake of a nutrient from food, water, and supplements if adverse effects have been associated with total intake. However, if adverse effects have been associated with intake from supplements or food fortificants only, the UL is based on nutrient intake from those sources only, not on total intake. The UL applies to chronic daily use. For many nutrients, there are insufficient data on which to develop a UL. This does not mean that there is no potential for adverse effects resulting from high intake. When data about adverse effects are extremely limited, extra caution may be warranted." (Food and Nutrition Board, Institute of Medicine. *Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients*. Washington, D.C.: National Academy Press. 1998.)

[18] Food and Drug Regulations, Part D, Division 1, Table

and minerals on the label is a powerful incentive for the industry to use them rather than to adjust their fortification levels to the latest RDAs from the National Academy of Sciences.

The harmonization of the science base underlying nutrition-related policies and programs through the new DRIs, which are being jointly developed by Canadian and U.S. scientists, could lead to increased harmonization in food composition and the addition of vitamins and minerals to foods, thus further facilitating trade between the two countries.

Consumer Protection (Control Criterion #5)

Consumer protection measures will be built into the implementation of the general provisions, for example, through the range of nutrient additions permitted, the selection of food vehicles and possibly provisions for co-fortification of nutrients. As with almost all instances where vitamins or minerals are added to foods, the total amount of any added vitamin or mineral contained in the food would have to be declared on the label. Further consumer protection would be accomplished through appropriate nutrition labelling and advertising.

IMPLICATIONS FOR IMPLEMENTATION OF THIS RECOMMENDATION

Need for Research and More Data

Reliable data on food, nutrient intake and nutritional status of Canadians are necessary to ensure that decisions are science-based.

Monitoring

Implementation of this recommendation could result in an increasingly complex food supply. Nutrition surveillance programs would be needed to assess effectiveness in achieving the intended benefits and to anticipate potential adverse effects.

Education

Implementation of this recommendation will require new consumer education about nutrition and how to use fortified foods as a part of healthy eating. Because food fortification is optional under this recommendation, consumers may find it difficult to know whether they should select fortified products or not. Education programs would also be required to avoid having people view fortified foods as a "magic bullet" that could replace healthy eating.

Regulatory Implementation

Recommendation 1(c) has the stated objective of expanding fortification programs to allow for a wider range of products with added vitamins and minerals to help Canadians meet the DRIs. It is proposed that this recommendation be implemented mostly by employing regulations which would permit the addition of vitamins and minerals to unstandardized foods within a range based on the RDAs and ULs. Minimum levels would be based on an amount that makes the food a significant source of a nutrient; maximum levels, which would include overages, would be based on risk and potential benefit. Premarket review would not be required if the product fits within the established minimum and maximum levels. Thus, certain prior assumptions would be made that these nutrients, added to foods at these levels will, in general terms, help Canadians meet the DRIs. Within this model, it may be desirable to include a requirement for co-addition for certain nutrients (e.g. where addition of one nutrient alone could reasonably be expected to adversely affect other nutrients in the food supply).

Outside the limits of nutrient addition that might be established by general regulations, there may be situations where higher levels are justified for the same basic objective (i.e. to help Canadians—here assumed to mean the general, healthy population—meet the DRIs). Applications for such products would be dealt with on a

case-by-case basis and an amendment made to the Regulations as required. Where the needs of a population sub-group differ greatly from the general population, the addition may better fit under the category of Special Purpose Foods, Recommendation 1(d).

Implementation would vary by nutrient and its risk profile, and might proceed as follows:

STEP 1: ***Classify nutrients according to risk profile.***

All vitamins and minerals for which there is a recommended intake would be classified. For nutrients with ULs, consideration will be given to:

- margin of safety between requirement and UL;
- severity of the adverse effect(s) on which the UL is based; and
- the need for limits on how much and in which food(s) nutrients should be added to ensure that efforts to provide more sources for some segments of the population do not result in ULs being exceeded in other population sub-groups.

For nutrients for which the Food and Nutrition Board of the National Academy of Sciences has not established ULs, scientific judgement will have to guide their handling as Group I or II (as described below). In many cases, when the National Academy of Sciences has found little or no adverse effect associated with high intakes from supplements, this information can be used to set the appropriate maximum level. The nutrients regulated under Group I could expand as further ULs are established during the DRI reviews.

STEP 2: ***Group the nutrients for regulatory purposes according to the results of Step 1.***

As an example,

- **Group I** – Nutrients with minimum and maximum levels specified: The minimum would be based on the amount that makes the food a significant source; the maximum would vary by nutrient and be based on risk and potential benefit. These maximum levels for each nutrient could be set as a proportion of the RDA per serving, per reference amount or per unit of energy. As the risk increased, the maximum would decrease. Depending on the nutrient, the limits may be applied to different foods or groups of foods.
- **Group II** – Nutrients that would continue to be subject to individual regulations governing specific nutrient levels and specific foods, as currently done for all nutrients and foods.

In general,

- unless a nutrient is included in Group I, the default position would be Group II. As many nutrients as possible would be included in Group I to reduce the need for individual regulations and evaluations. Maximum levels would be established to minimize risk associated with over-consumption;
- the need for co-fortification or appropriate ratios of nutrients will be considered in both cases; and
- the foods would be required to meet the criteria for food vehicles as set out under Recommendation 3.

RECOMMENDATION 1(d)

It is recommended that the category of special purpose foods be developed to allow for the addition of vitamins and minerals to foods to make a greater variety of products to fulfil a wide range of nutritional purposes.

EXPLANATION AND INTENT

The Codex *General Principles for the Addition of Essential Nutrients to Foods* refer to a category of foods for which addition of essential nutrients is justified, called "special purpose foods". The definition is:

> *"foods that have been designed to perform a specific function, such as to replace a meal which necessitates a content of essential nutrients which cannot be achieved except by addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use."*

The Food and Drug Regulations already make provision for certain types of special purpose foods. They include meal replacements, formulated liquid diets, nutritional supplements and others. The intent of Recommendation 1(d) is to make use of the above Codex definition to increase the opportunities under the Regulations for developing new products with added vitamins and mineral nutrients that would not be provided for under Recommendations 1(a) to 1(c), but where these additions are justified for other nutritional purposes.

RATIONALE IN SUPPORT OF THIS RECOMMENDATION

Population Health (Screen Criterion #1)

Guiding principle #1 of the present document states that the policy must ensure that the addition of vitamins and minerals to foods aims "...to protect and enhance the health of the population, including sub-groups at identified risk." Special purpose foods provide a mechanism for addressing the needs of some of these sub-groups. These include certain demographic sub-groups (e.g. elderly persons or premenopausal women, whose recommended intakes are substantially higher for certain nutrients than the rest of the population); people with certain chronic conditions or diseases; and people who, for religious, cultural preference or other reasons, do not consume certain nutritious foods or food groups. Other products may address circumstances that are less related to supporting general health but meet other nutritional purposes, such as sports nutritionals.

Safety and Effectiveness (Screen Criterion #2)

The basis for regulating the category of special purpose foods will be the application of requirements for the use of appropriate labelling to indicate for whom the food is intended and for what purpose, and to provide directions that guide the consumer toward its appropriate and safe use. The levels and combinations of nutrients added will need to be justified for the purpose intended. This means that a scientific rationale would have to be submitted to support the product's composition and its targeting, and show that the product is an effective way of fulfilling the claimed function.

Adding nutrients to foods that will be targeted to a specific group of people is a way to meet the specific dietary needs of those people. At the same time, identifying the intended user group on the label will help to limit the potential for unnecessary or harmful over-consumption of nutrients by people who do not have those specific needs.

This category of foods is not meant to be a way to introduce ultra-high levels of nutrients into foods. Safety assessment will be based on considerations of the recognized ULs for nutrients, nutrient interactions, how the product will be used in the diet and the potential for non-intended users to consume the product. Neither labelling nor education removes the need to control the sale of unsafe products. Providing warnings or directions for use

that are intended in part to reduce the risk of product misuse has little history of use for food products, which are expected by consumers to be inherently safe.

Availability and Choice (Control Criterion #1)

These products will possibly cost more than regular products. This could mean that some people would not have access to these products; however, the market would be expected to be the main determinant of price. Overall, the implementation of this recommendation would be expected to result in increased choice in the marketplace.

Codex General Principles (Control Criterion #2)

The Codex *General Principles for the Addition of Essential Nutrients to Foods* make reference to "special purpose foods." (See definition above.)

The Principles also advise that:

> 7.1 Nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content. Where appropriate, such addition should be made with due regard to the nutrient density of such foods. (CAC/GL 09-1987)

Trade and Competitiveness (Control Criteria #3 and #4)

Under this recommendation, it should be possible to permit the sale of products with higher concentrations of vitamins and minerals or other nutritional features that would not be suitable under Recommendation 1(c), above. This approach should provide opportunity for greater flexibility in product development than is currently the case, and hence increase trade and competitiveness of the Canadian food industry.

Consumer Protection (Control Criterion #5)

The labelling requirements that are intended to be a basic part of the characterization of this group of foods are aimed at helping consumers understand the appropriate and safe use of the product. They will, however, also be designed to avoid misleading consumers about the nature of the foods and the potential benefits that might be obtained from them. Aside from this, the same basic requirements for declaring the added nutrients on the label, etc., will apply to these foods as to other foods with added vitamins and minerals.

IMPLICATIONS FOR IMPLEMENTATION OF THIS RECOMMENDATION

Education

Education will be needed to inform consumers about the existence of such products, how to use them appropriately, and how to understand the labels.

Monitoring

Implementation of this approach might result in an increasingly complex food supply. Ideally, implementation would involve nutrient intake monitoring to assess the effectiveness in achieving the intended benefits as well as to anticipate potential adverse effects. A HACCP approach (see Section 3 Other Considerations, subsection (iii) Compliance Programs for a brief description) may be an appropriate way to implement inspection and compliance programs regarding the addition of vitamins and minerals to foods.

Regulatory Implementation

New options for marketing products as special purpose foods are envisaged under this recommendation. Addition of vitamins and minerals to foods has, in the past, generally been viewed as having to have a goal pertinent to the general public or to individuals requiring special foods to help with the dietary management of a disease or disorder. Because special purpose foods will, through controlled labelling and advertising, target subgroups of the population to address a range of nutritional purposes, this will permit the elaboration of more specially designed "niche" products. Nevertheless, it must

be remembered that a scientifically supported nutritional rationale will be required to justify these products. Opening up this category represents a response both to developments in scientific knowledge and to consumer, health sector and food industry interest in nutritious, health enhancing foods. Since more products with added vitamins and minerals will also be permitted under 1(c), however, this category would still be reserved for addressing special purposes, outside the limits provided for in 1(c).

New regulatory provisions to implement Recommendation 1(d) are expected to include both specific regulations for new defined sub-categories of special purpose foods and provisions that outline the conditions for creating a special purpose food and the requirements for making submissions for special purpose foods that do not fit into established sub-categories. The current regulations for meal replacements that indicate the minimum and maximum amounts of nutrients that must be in the products as well as labelling requirements are an example of specific regulations.

It is proposed that the following conditions be satisfied to permit a food to contain added vitamins or mineral nutrients under this approach and that these conditions be made part of the Regulations.

1. a) The label must carry clear identification of the use or purpose of the food, including both for whom and for what purpose it is intended.
   b) There must be a rationale for the addition of the nutrient(s) and the addition of the nutrient(s) must be necessary for the food to perform its intended purpose.
2. The label must carry clear and adequate directions for use to guide the consumer in the safe and appropriate use of the product.
3. The format and formulation of the product must be appropriate to its intended purpose.
4. The claim or statement of purpose must be justified by valid scientific evidence.

The kinds of products that may be introduced under this category are quite varied. Current categories, as mentioned previously, include the following special dietary foods: meal replacements; formulated liquid diets such as those used for patients who cannot eat normal foods or for people with metabolic disorders such as phenylketonuria; nutritional supplements; and such foods as enriched gluten-free bread. Special purpose foods could also include foods for population sub-groups that have higher needs for certain nutrients than other sub-groups for whom intakes at those levels might be excessive. This might include, hypothetically, a breakfast cereal high in iron directed at premenopausal women for whom a high intake is desirable but which would be undesirable for men. Another example could be a prune juice aimed at older adults that has vitamin D and vitamin B_{12} added to it. The new RDA for vitamin D for people over 50 years of age is three times the RDA for younger adults and this group is also advised to obtain the RDA of vitamin B_{12} in a synthetic form, whereas this is not generally necessary for younger people. Also, special purpose foods could be designed for people who are under high physical stress due to athletic activity (sports nutritionals), or could include products designed to help reduce the risk of disease or have beneficial effects on the structure or function of the body (functional foods).

There may be products that need to carry warnings but this should be used only as a risk management tool in the most compelling circumstances. Products on the open market should be designed to be essentially safe. On the other hand, labelling that informs the consumer about who the target group is and the purpose of the food must be clear.

While new categories and definitions are likely to be added, the provisions in the Food and Drug Regulations that currently exist for products that are foods for special dietary use will likely be retained.

RECOMMENDATION 2

It is recommended that addition of vitamins and minerals to foods not be permitted where no adequate nutritional rationale can be provided.

EXPLANATION AND INTENT

In making this recommendation, Health Canada is not proposing that evidence of a health benefit be submitted to justify nutrient addition in general. The essentiality of essential nutrients is well established and, provided they are being added to foods to help people achieve their recommended intakes or for one of the other recognized purposes discussed in this paper, a further clinical measurement of health benefit is not necessary. However, if a product is to carry a health claim, standards of evidence established for health claims would have to be met.

Throughout the consultation phases of this policy review, the message was clearly conveyed that the addition of nutrients to foods should not be treated lightly and that, apart from the potential for adverse effects due to over-consumption or nutrient imbalances, allowing unfettered addition of vitamins and minerals to foods would tend to trivialize the role that nutrients play in nutrition. This recommendation establishes a boundary for the addition of vitamins and minerals to foods. Without it, there is a risk that the addition of vitamins and minerals to foods would become disconnected from nutritional need, health benefit or purpose. Addition of vitamins and minerals to foods at levels that cannot be nutritionally justified would carry an implicit message to consumers that some benefit may accrue from consumption of micronutrients at those levels. Such a system would be inconsistent with the Codex *General Principles for the Addition of Essential Nutrients to Foods* and with the guiding principles for this policy review, in particular Guiding Principle 4 which states "The policy must help to prevent practices that may mislead, deceive or confuse the consumer, and yet facilitate consumer choice." All guiding principles were strongly supported by the broadly representative stakeholder group in attendance at the March 1998 Consultation Workshop.

RATIONALE IN SUPPORT OF THIS RECOMMENDATION

Without this recommendation, food fortification could potentially seriously undermine the concept of the total diet by encouraging consumers to rely on only a few, highly fortified foods rather than a well-balanced diet consisting of a variety of foods consumed in moderation. This could create the illusion of healthy eating, while limiting or adversely affecting the consumption of other nutritious components of the diet such as fibre or phytochemicals whose roles and benefits are not yet clearly established.

Several issues could complicate the management of risk associated with the addition of vitamins and minerals to foods at levels that cannot be adequately nutritionally justified. It is believed that foods in general are not consumed with the same degree of discretion that is associated with supplements in more traditional pharmaceutical forms (e.g. pills), and there may be a considerable likelihood for consumption of multiple servings (beyond label directions) because consumers like the taste of the product or because "dosage" (i.e. serving size) for foods is highly variable. The use of warning labels on foods giving restrictions on use or "number of doses" is a situation with which there is little experience and no guarantee of effectiveness, and should be used only in the most compelling of circumstances. Such a system could result in loss of consumer confidence in the inherent safety of the Canadian food supply.

IMPLICATIONS FOR IMPLEMENTATION OF THIS RECOMMENDATION

Adequate nutritional rationales will enter into the decision process used to establish minimum and maximum

levels for general regulations for addition of vitamins and minerals to foods, particularly under Recommendations 1(c) and 1(d). Submissions seeking provision for addition of vitamins and minerals to foods outside the levels provided for in the general regulations will be required to be accompanied by adequate justification of the nutritional rationale for the level(s) of addition being sought.

RECOMMENDATION 3

To avoid promoting consumption of foods that might increase risk factors for certain diseases or that have little nutritional value, it is recommended that criteria be applied to the selection of appropriate food vehicles for nutrient addition.

A) Food Vehicle

EXPLANATION, INTENT AND RATIONALE

During consultations, stakeholders expressed concerns that indiscriminate addition of nutrients to foods such as confectioneries, snack foods, soft drinks, condiments and jams/jellies could result in deceptive and misleading claims to the consumer. For example, participants were concerned that the addition of vitamins and minerals to foods with low nutrient density or foods high in fat, which would then be promoted for the added nutritional value, would be confusing to consumers. There is great potential to confuse consumers if foods such as confectioneries, soft drinks, high fat desserts and snack foods are claimed to be a source of added nutrients while *Canada's Food Guide to Healthy Eating* states that these foods should be used in moderation. It was pointed out that promoting an increased consumption of these foods would make it more difficult for consumers to follow current dietary guidelines and establish healthy eating patterns.

Participants at the November 23 to 25, 1998 stakeholder consultation and members of the EAP discussed different solutions to overcome these concerns. It was generally agreed that criteria were needed to clarify which foods were appropriate vehicles for the addition of vitamins and minerals. It was also felt that these criteria should be specific enough to avoid implementation problems. Thus, the criteria chosen must help to clearly identify appropriate foods for fortification without leaving too much room for ambiguity. Concepts examined during the review process but not retained included: (i) creating a definition of a "fun food"; (ii) identifying foods which are not part of the four food groups of *Canada's Food Guide to Healthy Eating*; and (iii) restricting fortification by specified intended use of a food. It was felt that implementation of these concepts would be impossible, as none could be used to establish clear criteria for food selection.

In the U.S., the Food and Drug Administration (FDA) has also considered that "foods bearing health claims should be those consistent with dietary guidelines, and that the value of health claims should not be trivialized or compromised by their use on foods of little or no nutritional value." These objectives are similar to those raised during our consultation discussions on food vehicles. Food compositional criteria were developed by the FDA to meet these objectives and are now part of the General Requirements for Health Claims for Foods in CFR 21 §101.14(a)(5) and §101.14(e)(6). The WG and EAP felt that these criteria could serve as a model to develop compositional criteria for the selection of appropriate food vehicles for the addition of vitamins and minerals in Canada. The details provided in the following section describe the application of these U.S. requirements within the context of Canadian dietary guidance.

Despite the concerns stated above, stakeholders recognized that foods of low nutritional value and foods with high levels of those nutrients for which reduced intake is desirable could also be potential vehicles for reaching specific groups in certain circumstances (e.g. fruit-flavoured drinks and whole milk). Thus, it is

recommended that the use of criteria for the selection of appropriate food vehicles primarily apply to the implementation of Recommendations 1(c) and 1(d). This recognizes that there are and may continue to be exceptions to these criteria. However, selection of a food vehicle which is not consistent with these criteria would have to be supported by a strong public health rationale. This measure will support current dietary guidelines while allowing for exceptions in specific circumstances.

IMPLICATIONS FOR IMPLEMENTATION OF THIS RECOMMENDATION

Proposed criteria for selecting food vehicles for nutrient addition:

Appropriate food vehicles are foods that provide the required level for at least one of the "qualifying" nutrients and do not contain more than the specified levels for any of the "disqualifying" nutrients.

The following qualifying and disqualifying nutrient levels were chosen to allow the addition of nutrients to a variety of foods in all food groups which are a significant part of a balanced and healthy diet:

"Qualifying nutrient levels"

Nutrients should not be added to a food unless the food contains, naturally or through restoration, per reference amount customarily consumed, 10% or more of the Weighted Recommended Nutrient Intake (WRNI)[18] for at least one nutrient.

"Disqualifying nutrient levels"

A food should not be fortified if any of the following "disqualifying nutrient levels" are exceeded per reference amount, per labelled serving and, for foods with reference amounts equal to or less than 30 ml or 30 g, per 50 g:

- fat: 13 g (19.5 g for entrees and prepackaged meals); or
- sum of saturates and trans: 4 g (6 g for entrees and prepackaged meals); or
- sodium: 480 mg (720 mg for entrees and prepackaged meals).

Nutrition Recommendations for Canadians state that the Canadian diet should include no more than 30% of energy as fat (66 g fat/2000 kcal) and no more than 10% as saturated fat (22 g based on a 2000-calorie diet). The above food-related levels are equivalent to 20% of these amounts. Nutrition Recommendations do not include a quantitative limit on sodium intake but do recommend that Canadians "limit salt." A recent report sponsored by the Canadian Hypertention Society, the Coalition for High Blood Pressure Prevention and Control, the Laboratory Centre for Disease Control at Health Canada, and the Heart and Stroke Foundation of Canada similarly recommended that the general public avoid excessive salt intake.[19] This report, while not recommending a specific sodium restriction level for normotensive adults, identified 90-130 mmol/day (2000-3000 mg/day) of sodium as the target level for hypertensive adults, 44 and older. Since the US reference value of 2400 mg falls midway within this range, it would appear to be an appropriate figure to adopt as the reference value for the present purpose.

As part of the review of Canadian nutrition labelling policy, fat, saturates, trans fatty acids and sodium have been identified as nutrients of sufficient public health

II and Division 2, Table II. WRNIs were calculated by determining the proportion of the population made up by each age/sex group using the census data of either 1986 or 1991 and multiplying these percentages by the respective Recommended Nutrient Intakes from the 1990 Nutrition Recommendations. (See Appendix M.)

[19] Fodor, I.G., B. Whitmore, F. Leenen, and P. Larochelle. 5. Recommendations on dietary salt. CMAJ. May 4. 160 (9 suppl):S29-S34, 1999.

importance to be in the core list of nutrition labelling. Therefore, these nutrients provide an appropriate basis for a criterion to preclude foods that contain levels of nutrients that are not consistent with dietary recommendations, while allowing for fortification of foods whose increased consumption has been promoted in dietary guidelines (Appendix L).

B) Addition of Vitamins and Minerals to Commodity Foods

It is recommended that the above guidelines be applied to "traditional" fortification of commodity foods as well as the more processed foods.

Health Canada is not prepared at this time to make a recommendation about regulating the enhancement of vitamin and mineral levels through production technology as this is outside the scope of what is currently regulated as "addition" of vitamins and minerals to foods. This issue needs to be addressed under another forum such as novel foods, etc.

RECOMMENDATION 4

In the context of the recommendations stated above, the Codex General Principles should continue to be followed.

EXPLANATION, INTENT AND RATIONALE

The Codex Alimentarius Commission (Codex) is the international body responsible for the Joint FAO/WHO Food Standards Programme. This programme is aimed at protecting the health of consumers and facilitating international trade in foods. Codex is responsible for establishing standards, guidelines, codes of practice and other advisory texts concerning the safety and quality of foods. Canada is one of the165 member countries of Codex.

Reference to and endorsement of the Codex *General Principles for the Addition of Essential Nutrients to Foods* has been included in these policy recommendations for several reasons. The Codex General Principles (see Appendix A) are based on sound nutritional principles and provide definitions for the terms used in these policy recommendations. The Codex General Principles outline the basic principles appropriate to the approaches outlined in recommendations 1(a)–(d) above: restoration (Codex Section 4), nutritional equivalence (Section 5), fortification (Section 6), and special purpose foods (Section 7). These principles also address the full range of issues with respect to nutrient addition including safety, nutrient interactions, bioavailability, technical feasibility, and choice of food vehicle (Sections 3.2–3.11). In addition, the Codex General Principles are incorporated by reference into the Canadian Food and Drug Regulations with respect to the application of the IMA regulation.

Although Codex standards, guidelines and recommendations have been elaborated for voluntary adoption by countries, these texts are used as a reference in international trade by the WTO. The Agreements on Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS) encourage Members to base their technical regulations and SPS measures on relevant international standards. Although the TBT Agreement does not cite specific international standard setting bodies, the SPS Agreement references, for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission. Further details concerning Canada's obligations under these international trade agreements are given in Appendix H.

It is with this background in mind that it is considered to be appropriate for Canada to continue to follow the Codex General Principles.

RECOMMENDATION 5

In implementing the above recommendations, it is proposed that increased flexibility be incorporated into the regulatory framework controlling the addition of vitamins and minerals to foods by including alternatives to the current "positive listing" approach. These might include general regulations and/or premarket notification.

One reason for the current review of policies on the addition of vitamins and minerals to foods is that some health interest groups, sectors of the food industry and consumers view the regulatory controls on nutrient addition as being overly restrictive. There is a desire for more flexible controls to enable the industry to provide new, nutritionally enhanced products that may benefit consumers.

As discussed in the regulatory implementation sections following each recommendation, a variety of regulatory options is available to permit greater flexibility and freedom to develop new products. These include the establishment of ranges of permitted nutrient additions, general regulations for nutrient restoration and substitute foods, and premarket notification for special purpose foods. In a number of ways, these recommendations provide examples of increased flexibility at the regulatory level for realizing the potential benefits of addition of vitamins and minerals to foods, while maintaining the ability to address public health needs and protect the population from excessive or imbalanced intakes.

9 Implementation Plans

Once the new policy has been adopted, currently available regulatory mechanisms that apply to a given proposed product can be used to bring new products on the market with the least amount of delay. This would be expected to apply to products that meet the current criteria for an IMA or for which a TMAL would be justified (for details, see Section 3). Where entirely new regulations are needed, the process whereby amendments are published in *Canada Gazette, Parts I and II* will be followed. This would include the general provisions mentioned in Recommendation 1(a) that would allow for addition of nutrients for purposes of restoration, or to make substitute foods nutritionally equivalent, and for any new general provisions discussed under 1(c) and 1(d) related to ranges and premarket notification.

Appendices

Appendix A

Codex Alimentarius
Volume 4 - 1994, pp. 9–12

GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS CAC/GL 09-1987 (AMENDED 1989, 1991)[20]

INTRODUCTION

The *General Principles for the Addition of Essential Nutrients to Foods* are intended:

- To provide guidance to those responsible for developing guidelines and legal texts pertaining to the addition of essential nutrients to foods.
- To establish a uniform set of principles for the rational addition of nutrients to foods.
- To maintain or improve the nutritional quality of foods.
- To prevent the indiscriminate addition of essential nutrients to foods thereby decreasing the risk of health hazard due to essential nutrient excesses, deficits or imbalances. This will also help to prevent practices which may mislead or deceive the consumer.
- To facilitate acceptance in international trade of foods which contain added essential nutrients.

1. SCOPE

These principles are intended to apply to all foods to which essential nutrients are added.

2. DESCRIPTION

Definitions

For the purpose of these guidelines:

2.1 ***Nutrient*** means any substance normally consumed as a constituent of food:

1. which provides energy; or
2. which is needed for growth and development and maintenance of healthy life; or
3. a deficit of which will cause characteristic biochemical or physiological changes to occur.

2.2 ***Essential nutrient*** means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.

[20] Copied with permission from the Food and Agriculture Organization of the United Nations. *Codex Alimentarius Volume 4 – Foods for special dietary uses (including foods for infants and children)*. 2nd edition. Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission. Rome, 1994. pp. 9-12.

2.3 ***Nutritional equivalence*** means being of similar nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient(s) are present in the substitute or partially substituted food (extender) in comparable amounts.

2.4 ***Substitute food*** is a food which is designed to resemble a common food in appearance, texture, flavour and odour, and is intended to be used as a complete or partial replacement for the food it resembles.

2.5 ***Fortification or enrichment*** means the addition of one or more essential nutrients to a food whether or not it is normally contained in the food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

2.6 ***Restoration*** means the addition to a food of essential nutrient(s) which are lost during the course of good manufacturing practice, or during normal storage and handling procedures, in amounts which will result in the presence in the food of the levels of the nutrient(s) present in the edible portion of the food before processing, storage and handling.

2.7 ***Special purpose foods*** are foods that have been designed to perform a specific function, such as to replace a meal which necessitates a content of essential nutrients which cannot be achieved except by addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use.

2.8 ***Nutrient density*** means the amount of nutrients (in metric units) per stated unit of energy (MJ or kcal).

2.9 ***Standardization*** means the addition of nutrients to a food in order to compensate for natural variations in nutrient level.

3. BASIC PRINCIPLES

3.1 Essential nutrients may be added to foods for the purpose of:
3.1.1 restoration;
3.1.2 nutritional equivalence of substitute foods;
3.1.3 fortification;
3.1.4 ensuring the appropriate nutrient composition of a special purpose food.

3.2 The essential nutrient should be present at a level which will not result in an excessive or an insignificant intake of the added essential nutrient considering amounts from other sources in the diet.

3.3 The addition of an essential nutrient to a food should not result in an adverse effect on the metabolism of any other nutrient.

3.4 The essential nutrient should be sufficiently stable in the food under customary conditions of packaging, storage, distribution and use.

3.5 The essential nutrient should be biologically available from the food.

3.6 The essential nutrient should not impart undesirable characteristics to the food (e.g. colour, taste,

flavour, texture, cooking properties) and should not unduly shorten shelf-life.

3.7 Technology and processing facilities should be available to permit the addition of the essential nutrient in a satisfactory manner.

3.8 Addition of essential nutrients to foods should not be used to mislead or deceive the consumer as to the nutritional merit of the food.

3.9 The additional cost should be reasonable for the intended consumer.

3.10 Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available.

3.11 When provision is made in food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying the essential nutrients to be considered or to be required and the levels at which they should be present in the food to achieve their intended purpose.

4. NUTRIENT ADDITION FOR PURPOSES OF RESTORATION

4.1 Where the food has been identified as a significant source of energy and/or essential nutrients in the food supply, and particularly where there is demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling should be strongly recommended.

4.2 A food should be considered a significant source of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the recommended nutrient intake in a reasonable daily intake (or in the case of an essential nutrient for which there is no recommended intake, 10% of the average daily intake).[21]

5. NUTRIENT ADDITION FOR PURPOSES OF NUTRITIONAL EQUIVALENCE

5.1 Where a substitute food is intended to replace a food which has been identified as a significant source of energy and/or essential nutrients in the food supply, and particularly where there is demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be strongly recommended.

5.2 A food being substituted or partially substituted should be considered a significant source of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% of the recommended nutrient intake.

5.3 Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.

[21] This section remains under review.

6. NUTRIENT ADDITION FOR PURPOSES OF FORTIFICATION

6.1 Fortification should be the responsibility of national authorities since the kinds and amounts of essential nutrients to be added and foods to be fortified will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area.

6.2 The following conditions should be fulfilled for any fortification programme:

6.2.1 There should be a demonstrated need for increasing the intake of an essential nutrient in one or more population groups. This may be in the form of actual clinical or subclinical evidence of deficiency, estimates indicating low levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits.

6.2.2 The food selected as a vehicle for the essential nutrient(s) should be consumed by the population at risk.

6.2.3 The intake of the food selected as a vehicle should be stable and uniform and the lower and upper levels of intake should be known.

6.2.4 The amount of the essential nutrient added to the food should be sufficient to correct or prevent the deficiency when the food is consumed in normal amounts by the population at risk.

6.2.5 The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.

7. NUTRIENT ADDITION TO SPECIAL PURPOSE FOODS

7.1 Nutrients may be added to special purpose foods, including foods for special dietary uses, to ensure an appropriate and adequate nutrient content. Where appropriate, such addition should be made with due regard to the nutrient density of such foods.

Appendix B

POLICY REVIEW TIME LINES

TASK	*DATE*
Phase I - Define Scope, Prepare Draft Action Plan	Fall 1997-Winter 1998
• Communicate plans for Policy Review to stakeholders	January 5, 1998
• Establish Terms of Reference for External Advisory Panel	January 1998
• Invite nominees for External Advisory Panel	January 1998
Phase II - Establish External Advisory Panel	January 31, 1998
Phase III - Identify and Define Issues	
• Prepare Background Paper for Issue Identification and distribute to interested parties (posted on Health Canada website)	March 18, 1998
• Consult with interested parties to define issues (facilitated 1-day open workshop)	March 27, 1998
• Prepare and distribute report of above to participants and other interested parties (posted on Health Canada website)	May 22, 1998
Phase IV - Analyse Issues	
• Analyse issues and potential policy options based on outcomes of March 27th Consultation Workshop and input from EAP	June 24-25, 1998 and September 14-15, 1998
• Prepare background paper for evaluation of potential food fortification approaches and distribute to interested parties (posted on Health Canada website)	November 13, 1998
• Consultation workshop to evaluate potential food fortification approaches (facilitated 2½ -day open workshop)	November 23-25, 1998
• Prepare and distribute report of above to participants and other interested parties (posted on Health Canada website)	January 31, 1999
Phase V - Recommend Solutions(s)	
• Evaluate potential solutions/policy options	
• Develop implementation plans	
• Identify preferred policy recommendation; meeting of government WG and EAP to review policy recommendations and implementation plans	March 30, 1999
• Publish policy options and preferred policy recommendation for review and comment (posted on Health Canada website)	October 1999†
• Close of comment period	December 31, 1999
Phase VI - Implementation	Begin Fall 1999‡

† Originally circulated as Spring 1999
‡ Originally circulated as September 1, 1999

Appendix C

REVIEW OF HEALTH CANADA'S POLICIES CONCERNING THE ADDITION OF VITAMINS AND MINERALS TO FOODS INTERDEPARTMENTAL GOVERNMENT WORKING GROUP–MEMBER LIST

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Appendix D

REVIEW OF HEALTH CANADA'S POLICIES CONCERNING THE ADDITION OF VITAMINS AND MINERALS TO FOODS EXTERNAL ADVISORY PANEL–MEMBER LIST

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Appendix E

FOODS TO WHICH VITAMINS, MINERAL NUTRIENTS AND AMINO ACIDS MAY BE ADDED – SORTED BY REASON FOR ADDITION

(*Food and Drug Regulations*, Adapted from Table D.03.002)

(As of June 1998)

COLUMN I Food	COLUMN II Vitamin, Mineral Nutrient or Amino Acid	Pertinent Section of the Regulations
I. Restoration		
Flour, white flour, enriched flour or enriched white flour	Thiamine, riboflavin, niacin, vitamin B_6, *d*-pantothenic acid, iron, magnesium	B.13.001
Breakfast cereals	Niacin, vitamin B_6, folic acid, pantothenic acid, magnesium, zinc	B.13.060
Alimentary pastes	Thiamine, riboflavin, niacin or niacinamide, pantothenic acid, vitamin B_6, iron, magnesium	B.13.052
Precooked rice	Thiamine, niacin, vitamin B_6, folic acid, pantothenic acid, iron	B.13.010.1
Corn meal	Thiamine, riboflavin, niacin, iron	IMA, Nov. 1997
Skim milk with added milk solids, partly skimmed milk with added milk solids, (naming the flavour) skim milk, (naming the flavour) partly skimmed milk, (naming the flavour) skim milk with added milk solids, (naming the flavour) partly skimmed milk with added milk solids, skim milk, partly skimmed milk, skim milk powder	Vitamin A	Division B.8 (various)
Evaporated skim milk, concentrated skim milk, evaporated partly skimmed milk, concentrated partly skimmed milk	Vitamin A	B.08.011-.012
Partly skimmed goat's milk, skimmed goat's milk, partly skimmed goat's milk powder, skimmed goat's milk powder	Vitamin A	B.08.029(2)
Evaporated partly skimmed goat's milk, evaporated skimmed goat's milk	Vitamin A	B.08.029(4)
Processed liquid whole egg, dried whole egg, frozen whole egg, liquid yolk, dried yolk, frozen yolk, liquid egg white (liquid albumen), dried egg white (dried albumen), frozen egg white (frozen albumen), liquid whole egg mix, dried whole egg mix, frozen whole egg mix, liquid yolk mix, dried yolk mix, frozen yolk mix	Vitamin A, vitamin D, vitamin E, thiamine, riboflavin, niacin, vitamin B_6, folacin, vitamin B_{12}, pantothenic acid, calcium, phosphorus, magnesium, potassium, iron, zinc	B.22.038
Margarine and other similar substitutes for butter	Vitamin E	B.09.016
Dehydrated potatoes	Vitamin C	Part D*

* **Part D** refers to sections D.01.009, D.01.010, D.01.011 and D.02.009 which are general regulations stating the minimum and/or maximum amounts of specific nutrients that must be present in certain foods if one of those nutrients is added. These are used where no specific amounts are stated elsewhere in the Regulations. Quantities are based on the Reasonable Daily Intake of the food (Schedule K of the Regulations).

COLUMN I Food	COLUMN II Vitamin, Mineral Nutrient or Amino Acid	
II. Substitute Foods		
Infant formulas	Amino acids – alanine, arginine, aspartic acid, cystine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine Minerals – calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc Vitamins – alpha-tocopherol, biotin, *d*-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin K	B.25.054 and others
Simulated meat products, simulated poultry meat products, meat product extenders and poultry product extenders	Thiamine, riboflavin, niacin, pyridoxine, *d*-pantothenic acid, folic acid, vitamin B_{12}, iron, magnesium, potassium, zinc, copper, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, valine	B.14.073, B.14.085-.090 B.22.027-.029
Products simulating whole egg	Vitamin A, thiamine, riboflavin, niacin or niacinamide, vitamin B_6, *d*-pantothenic acid, folic acid, vitamin B_{12}, alpha-tocopherol, calcium, iron, zinc, potassium	B.22.032
Margarine and other similar substitutes for butter	Vitamin A	B.09.016
Fruit nectars, vegetable drinks, bases and mixes for vegetable drinks and a mixture of vegetable juices	Vitamin C	Division B.11 (various)
Fruit-flavoured drinks that are sold as a substitute for fruit juice or as a breakfast drink	Vitamin C, folic acid, thiamine, iron, potassium	B.11.150
Bases, concentrates and mixes that are used for making fruit-flavoured drinks that are sold as a substitute for juice or as a breakfast drink	Vitamin C, folic acid, thiamine, iron, potassium	B.11.151
Apple juice, reconstituted apple juice, grape juice, reconstituted grape juice, pineapple juice, reconstituted pineapple juice, apple and (naming the fruit) juice as described in section B.11.132, concentrated fruit juice except frozen concentrated orange juice	Vitamin C	Division B.11 (various)
Plant-based beverages	Vitamin A, vitamin D, vitamin B_{12}, riboflavin, calcium, zinc, vitamin B_6, vitamin C, thiamin, niacin, folacin, pantothenic acid, phosphorus, potassium, magnesium	IMA, Nov. 1997

COLUMN I Food	COLUMN II Vitamin, Mineral Nutrient or Amino Acid	
III. Fortification		
Flour, white flour, enriched flour or enriched white flour	Folic acid, calcium	B.13.001
Infant cereal products	Thiamine, riboflavin, niacin or niacinamide, calcium, phosphorus, iron, iodine	Part D*
Breakfast cereals	Thiamine, iron	B.13.060
Alimentary pastes	Folic acid	B.13.052
Corn meal	Calcium and folic acid	IMA, Nov. 1997
Margarine and other similar substitutes for butter	Vitamin D	B.09.016
Flavoured beverage mixes and bases recommended for addition to milk	Vitamin A, thiamine, niacin or niacinamide, vitamin C, iron	Part D*
Milk, milk powder, sterilized milk, (naming the flavour) milk, condensed milk	Vitamin D	Division B.8 (various)
Skim milk with added milk solids, partly skimmed milk with added milk solids, (naming the flavour) skim milk, (naming the flavour) partly skimmed milk, (naming the flavour) skim milk with added milk solids, (naming the flavour) partly skimmed milk with added milk solids, skim milk, partly skimmed milk, skim milk powder	Vitamin D	Division B.8 (various)
Evaporated milk	Vitamin C, vitamin D	B.08.010
Evaporated skim milk, concentrated skim milk, evaporated partly skimmed milk, concentrated partly skimmed milk	Vitamin C, vitamin D	B.08.011-.012
Table salt, table salt substitutes	Iodine	B.17.003
Goat's milk, goat's milk powder	Vitamin D	B.08.029(1)
Partly skimmed goat's milk, skimmed goat's milk, partly skimmed goat's milk powder, skimmed goat's milk powder	Vitamin D	B.08.029(2)
Evaporated goat's milk	Vitamins C, D, folic acid	B.08.029(3)
Evaporated partly skimmed goat's milk, evaporated skimmed goat's milk	Vitamins C, D, folic acid	B.08.029(4)
Mineral water, spring water, water in sealed containers, prepackaged ice	Fluorine	B.12.001

* **Part D** refers to sections D.01.009, D.01.010, D.01.011 and D.02.009 which are general regulations stating the minimum and/or maximum amounts of specific nutrients that must be present in certain foods if one of those nutrients is added. These are used where no specific amounts are stated elsewhere in the Regulations. Quantities are based on the Reasonable Daily Intake of the food (Schedule K of the Regulations).

COLUMN I Food	COLUMN II Vitamin, Mineral Nutrient or Amino Acid	
	IV. Special Purpose Foods	
Foods represented for use in a very low-energy diet	Vitamins – alpha-tocopherol, biotin, *d*-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin K Minerals – calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc	B.24.303
Meal replacements and nutritional supplements	Minerals – calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc Vitamins – alpha-tocopherol, biotin, *d*-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D	B.24.200 B.24.201
Formulated liquid diets	Amino acids – alanine, arginine, aspartic acid, cystine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine Minerals – calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc Vitamins – alpha-tocopherol, biotin, *d*-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B_6, vitaminB_{12}, vitamin C, vitamin D, vitamin K	B.24.102
Ready breakfast, instant breakfast and other similar breakfast replacement foods however described	Vitamin A, thiamine, riboflavin, niacin or niacinamide, vitamin C, iron	B.01.053 and Part D*

* **Part D** refers to sections D.01.009, D.01.010, D.01.011 and D.02.009 which are general regulations stating the minimum and/or maximum amounts of specific nutrients that must be present in certain foods if one of those nutrients is added. These are used where no specific amounts are stated elsewhere in the Regulations. Quantities are based on the Reasonable Daily Intake of the food (Schedule K of the Regulations).

Appendix F

FOOD AND DRUG DIRECTORATE
Department of National Health and Welfare
Ottawa, Canada

T.I.L. NO. 351
Date: April 28, 1971

To: All Food Manufacturers
Re: *Proposed Guidelines for the Addition of Nutrients to Foods*

Consumers customarily have relied on a varied diet of traditional foods to ensure an adequate intake of nutrients. Occasionally it has been necessary to add nutrients to certain foods to restore those lost in processing or to prevent nutritional deficiencies. During recent years increased interest has developed in new types of foods including snack foods, substitute foods and meal replacements, which may not have the nutrient content of traditional foods. Therefore, increased attention must be given to nutritional aspects of food standards. Accordingly, the Food and Drug Directorate has developed for discussion the following guidelines for the addition of nutrients to foods:

1. Vitamins, minerals and protein added to traditional foods should be present in amounts related to the purpose of the addition:

   a) to replace those nutrients lost in the course of good manufacturing practice if the amount originally present provided at least 10% of the daily requirement of these nutrients in a reasonable daily intake of the food. The amount added should compensate for that lost in processing.

   b) to correct a demonstrated deficiency of one or more of these nutrients in some segment of the population if such addition is the most effective means of correcting the deficiency. The amount should only be sufficient to correct the deficiency.

2. A food sold or used as a substitute for a traditional food that normally provides, in a reasonable daily intake of the food, at least 10% of the daily requirement of a nutrient (including calories) should contain an equivalent amount of that nutrient.

3. Foods sold or represented as meal replacements shall contain essential nutrients including calories in amounts related to the pur pose of the meal e.g., instant breakfasts and infant formulas.

4. Snack foods for which nutritional claims are made and which supply at least 200 calories in a reasonable daily intake, shall con tain essential nutrients in proportion to their caloric content. No nutritional claims should be made for unfortified snack foods or fun-foods.

For these guidelines, the daily requirement of a nutrient will be based on the Canadian Dietary Standard where such exists. A detailed listing will be available in the near future. A table of Reasonable Daily Intakes of various foods was passed by P.C. 1971-356 of February 23, 1971, and published in the *Canada Gazette*, Part II, of March 10, 1971. These were issued in T.I.L. No. 347 of March 19, 1971.

The Directorate is aware that the principles outlined above will require amendment of present regulations. We will be pleased to receive views and suggestions concerning these guidelines before proceeding with the amendments.

orig. signed by:
R.A. Chapman,
Assistant Deputy Minister

Appendix G

SUMMARY OF TYPE OF REGULATORY OR LEGISLATIVE CONTROLS ON ADDITION OF VITAMINS AND MINERALS TO ORDINARY FOODS IN VARIOUS COUNTRIES. RESULTS OF 1994 SURVEY CONDUCTED BY THE NORDIC COUNCIL OF MINISTERS [a]

Country	Legislation/ Regulations on nutrient addition	Legislation/Regulation based on:[b]				Remarks
		General permission	Individual Authorization	Notification	Free	
Australia	Yes	X				Foods.allowed nutrients and their levels specified
Austria	No (except salt)				X	Nutrient addition is free as long as no health hazards exist and labelling does not mislead or deceive
Belgium	Yes	X		X		Nutrient addition allowed for all foods but notification is needed. Minimum and maximum final levels of nutrients in foods are defined
Canada	Yes	X				Foods, allowed nutrients and their levels specified
Denmark	Yes	X*	X+			*For flours, oatcakes, cereals, juices ; +For everything else
Finland	Yes	X*	X+			*For margarines; +For everything else. Moving toward General Permission.
Germany	Yes	X				Addition of named vitamins permitted without limitations. For vitamins A and D, maximum levels given. Permissible nutrient compounds listed.

[a] Adapted from *Addition of Nutrients to Foods – Principles and Practices*, published by the Nordic Council of Ministers, Copenhagen, TemaNord 1995:643; and D.P. Richardson, The addition of nutrients to foods, Proc. Nutr. Soc., 56:807-825, 1997.

[b] *General Permission*: Where nutrient addition is regulated by legislation which specifies the foods and/or nutrients permitted. Levels of permitted nutrients might also be specified.

Individual Authorization: Where nutrient addition is not permitted unless permission is specifically applied for from the authorities.

Notification: Where nutrient addition is permitted but notification is required.

Free nutrient addition: Where there are no authorization procedures nor restrictions governing nutrient addition to foods, or no legislation.

Country	Legislation/ Regulations on nutrient addition	Legislation/Regulation based on:[b]				Remarks
		General permission	Individual Authorization	Notification	Free	
Greece	Yes	X*	X+			*For margarines, fat emulsions, salt; +For everything else
Iceland	Yes	X*		X+		*For margarines; +For everything else. New regulations being drafted
Italy	No		X			Nutrient addition allowed only if approved by Ministry of Health
Luxembourg	No				X	Nutrient levels should not be high enough to exceed RDI
Netherlands	Yes					Nutrient addition prohibited except compulsory additions to margarines and breadsalt and optional addition to salt but regulations changing: more liberal
Norway	Yes	X*	X+			*For margarines, butter, oils, salt and goat whey cheese; +For everything else
Sweden	Yes	X*	X+			*For fat reduced milk, oils, salt, flours, pasta, +For everything else
Switzerland	Yes (for vitamins)	X				Addition of named vitamins allowed to all foods, maximum limits set
UK	Yes	X			X	Addition not restricted, provided not injurious to health
USA	Yes	X*			X+	*Food standards and food additive regulations control what nutrients may be added. Substitute foods must be made nutritionally equivalent to food replaced or else food must be labelled "imitation". +Unstandardized foods

Appendix H

CANADA'S OBLIGATIONS UNDER INTERNATIONAL TRADE AGREEMENTS

- The Codex Alimentarius Commission (Codex) was created in 1962 by the Food and Agriculture Organization of the United Nations and the World Health Organization as an intergovernmental body with the objectives of protecting consumers' health and ensuring fair practices in the food trade. Codex is responsible for establishing standards, guidelines, codes of practice and other advisory texts concerning the safety and quality of foods. These standards, guidelines and related texts are intended for voluntary adoption by member countries. Canada is one of the 165 member countries of Codex.
- The World Trade Organization was established in 1994 during the Uruguay Round of Multilateral Trade Negotiations. As a Member of the WTO, Canada is committed to implement the obligations in the Multilateral Trade Agreements, including the Agreements on Technical Barriers to Trade (TBT Agreement) and Sanitary and Phytosanitary Measures (SPS Agreement). These Agreements both recognize that countries have the right to take measures necessary for the protection of human life and health.
- The scopes of the SPS and TBT Agreements differ. The SPS Agreement covers measures intended to protect human, animal or plant life or health. More specifically, it covers measures designed to protect human life or health from risks arising from food additives, contaminants (including pesticides, veterinary drugs and extraneous matter), toxins or disease-causing organisms in food and beverages, and to protect animals and plants from pests or diseases.
- The TBT Agreement covers technical regulations intended to fulfil legitimate objectives including, among other things, national security requirements; prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment.
- The TBT and SPS Agreements encourage Members to base their technical regulations and SPS measures on standards prepared by appropriate international standard setting bodies. Although the TBT Agreement does not cite specific international standard setting bodies, the SPS Agreement references, for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission. Technical regulations and SPS measures that conform with international standards and are applied to protect human health are presumed to be consistent with the provisions of these Agreements.
- WTO Members can choose not to base their technical regulations on international standards where such standards would be ineffective or inappropriate for the fulfilment of a legitimate objective. Members may also introduce SPS measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on international standards. Under both the TBT and SPS Agreements, Members may be required to justify the more stringent requirements if a trade dispute arises.
- The TBT Agreement requires Members, in respect of technical regulations, to extend the same treatment to imports from all other Members and to like products of national origin. Technical regulations shall not be more trade restrictive than necessary to fulfil a legitimate objective. The SPS Agreement requires Members to ensure that SPS measures are applied only to the extent necessary, do not arbitrarily or unjustifiably discriminate between Members and are not applied in a manner that would constitute a disguised restriction on international trade.
- The provisions of the NAFTA Agreement in SPS and TBT areas are very similar to those of the TBT and SPS Agreements under the WTO.
- More information can be found on the Web at <<www.wto.org>>

Appendix I

DIETARY REFERENCE INTAKES
Background Information

- The Dietary Reference Intakes (DRIs) are a set of scientifically based nutrient reference values that will be used by government agencies, non-governmental health agencies and health professionals in policy and program development. For instance, the DRIs will be used in the assessment of nutrient intakes of individuals or groups; the planning of feeding programs; development of nutrition education materials; formation of policy decisions on the fortification of foods, and formulation of supplements and special dietary foods.
- The development of the DRIs is under way at this time. They are being established by Canadian and American scientists, through a review process overseen by the U.S. National Academy of Science's Food and Nutrition Board (FNB).
- Health Canada is participating in the U.S. review of nutrient requirements. Health Canada has reviewed and made recommendations on nutrient requirements on a periodic basis since 1938, the last update being in 1990 as part of *Nutrition Recommendations: The Report of the Scientific Review Committee*. By 1994, it became clear that an update would soon be needed and, since the FNB was beginning a consultation process on the review of the Recommended Dietary Allowances, Health Canada decided that participating in the U.S. review would offer several advantages to Canada.
- The FNB DRIs will ultimately replace the Canadian Recommended Nutrient Intakes (RNIs). The aim of having American and Canadian scientists working together on this review was to achieve a set of harmonized dietary reference values for both countries.
- Like the current RNIs, the evidence considered in determining the DRIs includes, where available, evidence that relates nutrients to the prevention of disease and developmental disorders along with more traditional evidence of sufficient nutrient intake. On the other hand, evidence concerning the use of nutrients in the mitigation or cure of a disease or disability was not considered because that was beyond the scope of the project.
- Unlike the current RNIs which are a single number, DRIs are a set of numbers for different uses. These are Estimated Average Requirements (EAR), Recommended Dietary Allowances (RDA), Adequate Intakes (AI) and Tolerable Upper Intake Levels (UL). These are defined as follows[22]:

  Estimated Average Requirement (EAR): The daily intake value estimated to meet the requirement, as defined by the specified indicator of adequacy, in 50% of the individuals in a life-stage or gender group. At this level of intake, the other 50% of a specified group would not have its nutritional needs met.

[22] Source, unless otherwise indicated: National Academy of Sciences, Institute of Medicine, Food and Nutrition Board, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*, (prepublication copy), Washington, D.C.: National Academy Press, 1997.

Recommended Daily Allowance (RDA): The dietary intake level that is sufficient to meet the daily nutrient requirements of almost all individuals (97% – 98%) in a specific life-stage and gender group (if an EAR is established, an RDA is established).

Adequate Intake (AI): If sufficient scientific evidence is not available to calculate an EAR, the reference value established is an AI. The AI is based on observed or experimentally determined approximations of the average nutrient intake, by a defined population or sub-group, that appears to sustain a defined nutritional state, such as normal circulating nutrient values or growth. Contemporary concepts of reduction in disease risk are incorporated into the derivation of the AI. (No RDA is established when only an AI is available.)

Tolerable Upper Intake Level (UL): The UL is "the highest level of daily nutrient intake that is likely to pose no risks of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the risk of adverse effects increases. The term *tolerable intake* was chosen to avoid implying a possible beneficial effect. Instead, the term is intended to connote a level of intake that can, with high probability, be tolerated biologically. The UL is not intended to be a recommended level of intake. There is no established benefit for healthy individuals if they consume nutrient intakes above the RDA or AI. ULs are useful because of the increased interest in and availability of fortified foods and the increase use of dietary supplements. ULs are based on total intake of a nutrient from food, water, and supplements if adverse effects have been associated with total intake. However, if adverse effects have been associated with intake from supplements or food fortificants only, the UL is based on nutrient intake from those sources only, not on total intake. The UL applies to chronic daily use. For many nutrients, there are insufficient data on which to develop a UL. This does not mean that there is no potential for adverse effects resulting from high intake. When data about adverse effects are extremely limited, extra caution may be warranted." (Food and Nutrition Board, Institute of Medicine. *Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients*. Washington, D.C.: National Academy Press. 1998.)

Note that DRIs are reference values for healthy populations only.

For more information, please visit the Food Directorate web site at:
<<www.hc-sc.gc.ca/food-aliment/english/index>> and look for the "Dietary Reference Intakes" hotlink listed on the sidebar.

Appendix J

CLARIFICATION OF TERMS: TOTAL DIET AND TOTAL EXPOSURE

- **Total Diet** incorporates the wide range of foods that are part of Canadian food consumption patterns. It includes the four food groups (grain products, vegetables & fruit, milk products, meat & alternatives), plus an "other foods" group covering a wide range of dietary items and beverages that contribute to taste and enjoyment in eating. The value of increased food variety in ensuring essential nutrient adequacy and decreasing the risk of food toxicity (health-adverse factors in food are generally diluted when the foods eaten are varied) has been understood for some time. The total diet approach integrates current nutrition recommendations into food selection suggestions that meet the objectives for both nutrient adequacy and moderation of food consumption relative to risk for specific diet-related chronic diseases (Technical Group for the Review of Canada's Food Guide, 1990).[23] The focus on foods recognizes the beneficial aspects of foods beyond the known essential vitamins and minerals (e.g. fibre, phytochemicals, or other beneficial components of foods).

- **Total Exposure** is used to denote total oral exposure of nutrients from all sources. This term includes ingestion of nutrients from foods (as naturally occurring nutrients, food additives or food fortificants), water and as a component of supplements or over-the-counter drugs. In the derivation of Tolerable Upper Intake Levels the U.S. National Academy of Sciences, Food and Nutrition Board based the Dietary Reference Intakes on total intake of nutrients from these sources (Chapter 3, Development of Tolerable Upper Intake Levels, Dietary Reference Intakes for B Vitamins, 1998).[24]

[23] Health and Welfare Canada. *Action Towards Healthy Eating...Technical Report*. Reports of the Task Group and Technical Group on Canada's Food Guide and the Task Group on Food Consumption to the Communications/Implementation Committee. 1990.

[24] National Academy of Sciences, Institute of Medicine, Food and Nutrition Board, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. *Dietary reference intakes for thiamin, riboflavin, niacin, vitamin B_6, folate, vitamin B_{12}, pantothenic acid, biotin and choline*. (Prepublication copy). Chapter 3, A Model for the Development of Tolerable Upper Intake Levels. Washington, D.C.: National Academy Press, 1998.

Appendix K

RISK MANAGEMENT

Risk vs. Safety

Like all chemical agents, nutrients can produce adverse health effects and it is not possible to identify a single "risk-free" or "safe" intake level for a nutrient that can be applied with certainty to all members of a population. To evaluate the effectiveness or safety, one needs an estimate of exposure dose. The required precision of that estimate will depend on the margin of safety of the nutrient. Because there is no single scientifically definitive distinction between "safe" and "unsafe" exposures, this section should more correctly be termed "Risk Management."

What Is Risk Management?

Risk may be defined in general terms, as a measure of the harm to human health that results from being exposed to an agent, substance, process or product (or in other words, a hazard), together with the likelihood that the harm will occur. Agencies that are involved in health protection often use a formalized process for assessing and managing health risks. This process generally involves identifying specific hazards, estimating the associated level of risk, developing and analysing potential options for managing the risk, selecting and implementing a specific risk management strategy, and monitoring and evaluating the impact of this strategy.[25] Risk management decisions depend on risk assessments, but also involve the public health significance of the risk, the technical feasibility of achieving various degrees of risk control, and the economic and social costs of this control.[26]

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[25] Health Canada. *Risk Management in Health Protection (Draft), Revised HPB Risk Management Framework*, Phase II Report, 1997, p. 1.

[26] National Academy of Sciences, Institute of Medicine, Food and Nutrition Board, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B_6, Folate, Vitamin B_{12}, Pantothenic Acid, Biotin, and Choline*. (Prepublication copy). Washington, D.C.: National Academy Press, 1998, p. 3-2.

Appendix L

DISQUALIFIED FOODS

Part 1:

The following foods contain more than the disqualifying level for the nutrient mentioned. It should be noted that this is not an exhaustive list; instead, it provides examples for illustrative purposes of foods that would be disqualified. These food examples could not be fortified unless there were a strong public health rationale and provision were made for fortification in other regulations:

Fat (13 g)

- fats and oils
- nuts and seeds
- higher fat baked goods (including crackers)
- higher fat cereal products (e.g. regular granola cereals)
- higher fat desserts
- higher fat mixed dishes (>19.5 g of fat)
- higher fat snack foods

Saturated and trans fat (4 g)

- butter
- margarines made from partially hydrogenated fats
- high fat cheeses
- chocolates
- cream
- ice cream
- whole milk
- high fat luncheon meats
- high fat meat cuts
- high fat baked products or food items (e.g. cakes, cookies, crackers, snack chips, muffins, doughnuts, french fries) made from partially hydrogenated fats or highly saturated fats (coconut oil, milk fat, tallow, lard).

Sodium (480 mg)

- lower fat luncheon meats
- smoked and canned fish
- tomato and vegetable juices and cocktails
- salty lower fat snack foods

Part 2:

The following additional foods would be excluded because they contain less than 10% of the Weighted Recommended Nutrient Intake (WRNI)[27] for any nutrient with a recommended nutrient intake:

- muffins except bran muffins
- rice
- milk desserts, except ice milk, frozen yogurt and a few milk puddings
- a few vegetables such as cucumber, celery, eggplant
- a few fruit juices such as apple, cranberry and grape juices
- foods that are mostly sugars
- condiments and lower fat dressings
- beverages including water, tea, coffee and soft drinks

[27] Food and Drug Regulations, Part D, Division 1, Table II and Division 2, Table II. WRNIs were calculated by determining the proportion of the population made by each age/sex group using the census data of either 1986 or 1991 and multiplying these percentages by the respective Recommended Nutrient Intakes from the 1990 Nutrition Recommendations. (See Appendix M.)

Appendix M

WEIGHTED RECOMMENDED NUTRIENT INTAKES FROM PART D, FOOD AND DRUG REGULATIONS, USED AS A BASIS FOR DETERMINING THE SIGNIFICANT NUTRIENTS IN FOODS FOR PURPOSES OF RESTORATION AND SUBSTITUTE FOODS

Nutrient	*Weighted Recommended Nutrient Intake[28] (Canada FDR: D.01 Table II, and D.02 Table II)*
Vitamin A, RE	*870*
Vitamin D, mcg	*3*
Vitamin E, mg	*7*
Vitamin C, mg	*34*
Thiamin, mg	*1*
Riboflavin, mg	*1.2*
Niacin, mg	*16*
Vitamin B_6, mg	*1*
Folacin, mcg	*195*
Vitamin B_{12}, mcg	*1*
Pantothenic acid, mg	*5*
Calcium, mg	*780*
Iodide, mcg	*155*
Iron, mg	*10*
Phosphorus, mg	*885*
Magnesium, mg	*210*
Zinc, mg	*10*

[28] WRNIs became part of the Regulations in 1996. They were calculated by determining the proportion of the population made by each age/sex group using the census data of either 1986 or 1991 and multiplying these percentages by the respective Recommended Nutrient Intakes from the 1990 Nutrition Recommendations. The results for each nutrient were then summed to give the above figures.